

SERVICE LEVEL AGREEMENT:
THOMAS JEFFERSON UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION (ORA)

July 1, 2017

Table of Contents

Acronyms List	3
Section I – General Information and Objectives	5
SLA Purpose and Expectation	5
ORA Vision	5
ORA Mission	5
ORA Guiding Principles	5
ORA Structure.....	6
Section II – ORA Service Components.....	6
Expectations for Response	6
ORA Services	6
Section III – ORA Performance Metrics.....	7
Tracking Effectiveness.....	7
Key Performance Indicators.....	7
Pre-award	7
Post-award	7
Subawards	7
Contracts	8
Training.....	8
Faculty/Department Service Related Metrics.....	8
Escalation Procedures: Failure to Meet Performance Expectations.....	8
Section IV – SLA Maintenance	9
Conditions Requiring Maintenance	9
Periodic Review of SLA	9
Ad Hoc Maintenance Requests	9
SLA Modification Review	9
Appendix	10
I. High Level Business Processes	10
II. Roles and Responsibilities Matrix	22
III. Clinical Roles & Responsibilities Matrix	33
IV. Pre-Award Proposal Submission Standards.....	38
V. ORA Signature Authority	40

Acronyms List

1. **A/R:** Accounts Receivable
2. **Cayuse SP:** Cayuse Sponsored Projects
3. **CCR:** Central Contractor Registration
4. **CCRRC:** Cancer Clinical Research Review Committee
5. **CDA:** Confidentiality Disclosure Agreement
6. **CITI:** Collaborative Institutional Training Initiative
7. **COI:** Conflict of Interest
8. **CRA:** Clinical Research Administrator
9. **CTA:** Clinical Trial Agreement
10. **eRA:** Electronic Research Administration
11. **F&A:** Facilities and Administrative
12. **PO:** Purchase Order
13. **FAC:** Faculty Advisory Committee
14. **FFR:** Federal Financial Report
15. **GA:** Grants Administrator
16. **GL:** General Ledger
17. **HR:** Human Resources
18. **IACUC:** Institutional Animal Care and Use Committee
19. **ICR:** Indirect Cost Recovery
20. **IDC:** Indirect Costs
21. **IDE:** Investigational Device Exemption
22. **IDT:** Interdepartmental Transfer
23. **IRB:** Institutional Review Board
24. **JCRI:** Jefferson Clinical Research Institute
25. **JIT:** Just in Time
26. **MCA:** Medicare Coverage Analysis
27. **MDG:** Multidisciplinary Groups
28. **NCE:** No Cost Extension
29. **NIH:** National Institutes of Health
30. **NOA:** Notice of Award
31. **NSF:** National Science Foundation
32. **ORA:** Office of Research Administration
33. **OSD:** Online Salary Distribution
34. **OTT:** Office of Technology Transfer
35. **PAF:** Personnel Action Form
36. **PAR:** Personnel Action Request
37. **PI:** Principal Investigator
38. **PMS:** Payment Management System
39. **QCT:** Qualifying Clinical Trial
40. **R&D:** Research and Development
41. **RACE:** Research Administration Center of Excellence
42. **SAM:** System for Award Management
43. **SFRAR:** Salaried Faculty Recruitment Authorization Request
44. **SLA:** Service Level Agreement
45. **SPA0:** Sponsored Program Accounting Office



- 46. **TJU:** Thomas Jefferson University
- 47. **UPAS:** University Prior Approval System
- 48. **VPT:** Visit Payment Tracker

Section I – General Information and Objectives

SLA Purpose and Expectation

The purpose of this Service Level Agreement (SLA) is to establish the foundation for a cooperative partnership between the Office of Research Administration (ORA), Research Administration Center of Excellence (RACE), Jefferson Clinical Research Institute (JCRI), and the departments, and schools they serve.

This SLA will outline:

- The services that ORA offers and the working relationship between ORA, JCRI, RACE, SPAO, the departments, and schools served
- The key performance indicators used to measure the quality of service provided

ORA will work closely with RACE/JCRI and the departments to meet their research administration needs. Communication, feedback, and accountability are critical to ensure excellent service.

ORA Vision

Handling the business of research so faculty can perform the research.

ORA Mission

Jefferson's Office of Research Administration (ORA) assists researchers in applying for, and managing sponsored funding through our mission, which is:

To serve as the official point of contact for the various sponsors of scientific and scholarly activity.

To facilitate the relationship between Jefferson investigators and these sponsors.

To ensure sponsored projects are managed in accordance with sponsor regulations and Jefferson policies.

To provide education and resources to support the management of sponsored programs.

ORA Guiding Principles

1. Responsiveness
 - Always **COMMUNICATE**
 - **REPLY** to all communication within 24 hours
 - Keep administrators and investigators **INFORMED**
 - **ELEVATE** problems early to resolve issues
2. Courtesy
 - Speak **PROFESSIONALLY** and **KINDLY**
 - Treat other people with **RESPECT**
3. Knowledge
 - Give only answers you **KNOW** to be true
 - If you do not know the answer,

- **ASK** questions of your colleagues, or
 - **SEEK** the answer in regulatory documents
 - Be willing to **LEARN** the answers to new questions
4. The Extra Mile
- **HELP** the researchers JCRI and RACE do what they need to do
 - **LEARN** in advance
 - **ANTICIPATE** problems and address them early
5. Continuing Education
- **PROVIDE** professional development opportunities for ORA staff
 - **ENCOURAGE** staff members to take advantage of internal and external training opportunities

ORA Structure

Each department will have designated ORA/RACE/JCRI staff members to serve as a contact for, pre-award, post-award and contracting research administration needs. If your ORA contact is out of the office for a planned or unplanned absence, a designated back-up individual will be available to meet your needs from the same ORA team.

The current list of ORA teams and the departments they serve can be found on the Thomas Jefferson University ORA [website](#).

Section II – ORA Service Components

Expectations for Response

ORA staff will respond to any request (whether submitted by JCRI, RACE, a PI, Dept. Chair or Department Administrator) submitted within **one business day**, with the understanding that when RACE, JCRI, a PI, and Grants Administrator are actively working on a proposal, communication will be more frequent. In the event that your ORA staff member is out of the office on a planned or unplanned absence, ORA will have a designated back-up. This information will be included in out-of-office e-mail messages and voicemail.

While ORA staff will constantly strive to meet expected service goals, please be aware of the following annual events that may impact processing time:

- Increased financial reporting requirements due to the institution's annual budgeting process
- NIH proposal cycle deadlines
- TJU fiscal year closing

ORA Services

ORA will work with JCRI, RACE, SPAO, the departments, and the PI who will collaborate and collectively be responsible for the entire award life cycle. A detailed roles and responsibilities matrix is included in the Appendix.

Section III – ORA Performance Metrics

Tracking Effectiveness

Timely, efficient, and accurate service and accountability are critical components of ORA. To ensure we meet these goals, key performance indicators are tracked.

The key performance indicators will be monitored by ORA management on a monthly basis and officially assessed annually.

Key Performance Indicators

Pre-award

Service Level Measures
Percentage of Federal proposals received from RACE that are free of administrative errors
Number of Federal Proposals Submitted (New, Competing Renewal, and Resubmissions)
Number of Private NP and State and Local Proposals Submitted (New, Competing Renewal, and Resubmissions)
Average Turnaround time of all Agency Types from proposal receipt to proposal submission
Number of awards received/reviewed and submitted to Post-Award
Average turnaround time for Pre-Award to submit award information to Post-Award for account establishment

Post-award

Compliance Risk and Service Level Measures
Total number of transactions reviewed
Number of closeouts reviewed
Total number of cost transfers reviewed
Number of cost transfers reviewed but not approved
Number of <i>late</i> cost transfers with no extenuating circumstances
Number of OSD's & PAF's reviewed
Number of new account establishments
Average turnaround time for post-award to establish account

Subawards

Service Level Measure
Percentage of PI Certifications for active subawards received on time (January, April, July, October)
Number of subawards issued
Number of subawards fully executed
Number of invoices reviewed
Number of invoices processed

Contracts

Service Level Measure
Number and type of Agreements Received
Number and type of Agreements Executed
Average turnaround time of agreements process to execution

Training

Service Level Measure
Number of courses offered
Number of courses updated
Number of live training sessions offered
Number of new employees on-boarded (RACE and ORA)

Faculty/Department Service Related Metrics

Service Level Measure
Research Intensive Faculty and Department Administrator satisfaction with ORA support (annual survey)

Escalation Procedures: Failure to Meet Performance Expectations

In the event ORA fails to meet the expectations outlined in this document, a PI, Chair, Dean, RACE, JCRI or Department Administrator can take the following steps:

1. **Communicate the problem directly with your assigned ORA representative**
Strong communication is the key to the success of the partnership between JCRI, RACE, the Departments and ORA. If a problem arises, the first step is to identify it specifically and discuss possible resolutions with your assigned ORA representative.
2. **Contact the appropriate ORA Associate Director**
If discussions with your ORA representative fail to resolve the problem or if the issues become pervasive, contact the appropriate ORA Associate Director (the individual's direct supervisor). If you do not know to whom your ORA contact reports, refer to the ORA [website](#).
3. **Contact the Director of Research Administration**
If discussions with the appropriate ORA Associate Director fail to resolve the problem, please contact the Director of Research Administration to discuss the problem and identify a resolution.

Section IV – SLA Maintenance

Conditions Requiring Maintenance

The SLA should accurately reflect the services provided by ORA staff to the departments and offices they serve. As processes and policies evolve, changes to services and service levels may be required. Updates and changes to the SLA can be identified, presented, and confirmed through the processes described below.

Periodic Review of SLA

The Vice President of Administration will review the SLA at least annually to determine whether the services and service level commitment are meeting the needs of the research community and the University.

Substantial changes in the institution, such as a significant increase in sponsored research, should also prompt a review of the SLA.

Ad Hoc Maintenance Requests

The Vice President of Administration, FAC, Department Chairs, Department Administrators and Deans can propose changes to the SLA outside of the regular review process. This review process is outlined as follows:

SLA Modification Review

The SLA will be reviewed for proposed changes/revisions and to consider any outstanding resource needs. The reviewers include: the Vice President of Administration and Director of ORA.

The Vice President of Administration, FAC, Department Chairs, Department Administrators and Deans may submit requested updates and recommendations to the Director of ORA, with a brief rationale for each recommendation. Requests will be reviewed and all approved changes will be incorporated within the SLA. The SLA will be posted on the ORA [website](#) to promote accountability. The Director of ORA will be responsible for implementing changes to the SLA and communicating SLA changes to their stakeholder group.

Appendix

I. High Level Business Processes

The chart below outlines the high level business processes performed by ORA and the PI/Departments whom they serve – clinical trials business processes begin on p. 16. A detailed Roles & Responsibilities Matrix is contained in Appendix II.

Pre-Award Services

Process	ORA Responsibilities	RACE Responsibilities	PI/ Department Responsibilities
Proposal Review and Submission	<ul style="list-style-type: none"> • Reviews the application for compliance with the sponsor's requirements and Jefferson's policies and procedures relating to fiscal requirements as well as human subjects and vertebrate animals certifications/assurances • Reviews information within the organizations award management system (i.e., Cayuse SP) for adherence to all TJU compliance issues and proper approvals • Conducts final approval and submission to sponsor after any required changes have been made by RACE • Review level to be determined by timeframe in which the proposal is received by ORA (See Section IV) 	<ul style="list-style-type: none"> • Compiles final proposal package ensuring most current forms, correct fonts and margins are being used, reviews, and routes Cayuse SP record for approval; obtain required documentation for subrecipients (Subrecipient versus Contractor Checklist, Subrecipient Commitment Form, Scope of Work, Budget, and F&A agreement) 	<ul style="list-style-type: none"> • Dept. Chair and Senior Administrator approve the Cayuse SP record (Dept. is confirming that PI is allowed to submit the proposal, and that the department is committing appropriate resources)
Just in Time Submissions	<ul style="list-style-type: none"> • Reviews the JIT materials for completeness and compliance with the sponsor's requirements and Jefferson's policies and procedures • Submits JIT materials to sponsor if submission by ORA is required 	<ul style="list-style-type: none"> • Prepares all administrative components of Just in Time or other pre-award requests from the sponsor • Facilitates regulatory approvals required for Just in Time submissions • Submits all materials to ORA or Sponsor, as appropriate 	<ul style="list-style-type: none"> • PI prepares all scientific components of JIT submissions • PI can delegate RACE GA to assist with JIT in eRA Commons, if desired

Process	ORA Responsibilities	RACE Responsibilities	PI/ Department Responsibilities
<p style="text-align: center;">Award Acceptance</p>	<ul style="list-style-type: none"> • Negotiates terms as needed, reviews for compliance, reviews award budget and routes to Post-Award • Notifies RACE if updated regulatory documents are needed or budget revisions are required • Reviews subaward documents if applicable and flags for the research administrator for subcontracts 	<ul style="list-style-type: none"> • Reviews award document and determines if revised budget is required • Facilitates regulatory approvals required to accept award • Revises budget based on awarded amount (if budget varies from proposed budget) if required, obtains revised budgets from Subrecipients 	<ul style="list-style-type: none"> • PI approves revised budget, if necessary • PI meets with RACE Grants Administrator to review award terms and conditions and grant purchasing guidelines • Department Senior Administrator is notified of significant budget changes
<p style="text-align: center;">Progress Report Submissions</p>	<ul style="list-style-type: none"> • Completes monthly check in Commons of all pending RPPRs due in the next month for NIH reports, forwards list to post-award for carryover check • Reviews progress reports for accuracy and compliance with sponsor's requirements, and verifies with post award the reported effort of project personnel • Facilitates regulatory approvals required for Progress Report submissions • Approves and submits all required materials to Sponsor 	<ul style="list-style-type: none"> • Completes monthly check in Commons of all pending RPPRs due in the next month for NIH reports, send notification to PIs indicating ORA due date • Beginning 30 days prior to the due date of a progress report (or 45 days for paper submissions), prepares all administrative components for Progress Report submissions • Facilitates regulatory approvals required for Progress Report submissions • Submits all materials to ORA or Sponsor, as appropriate 	<ul style="list-style-type: none"> • PI prepares all scientific components of Progress Report submissions (including ensuring the proper publications are linked in accordance with the NIH Public Access Policy) • PI can delegate RACE GA to assist with a Progress Report in eRA Commons if desired

Post-Award Services

Process	ORA Responsibilities	RACE Responsibilities	PI/ Department Responsibilities
Account Establishment	<ul style="list-style-type: none"> Generates the account establishment memo, completing all data points; distributes to PI, JCRI, RACE, department, and maintains the official copy in ORA Notes committed level of effort & special terms and conditions on hard file alert sheet Confirms specific Cayuse SP information and updates Cayuse SP record. 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> N/A
Establishment of Subawards	<ul style="list-style-type: none"> Develops subcontract agreements in accordance with the terms & conditions of the Prime sponsor. Ensures compliance with Federal requirements such as FCOI, annual audit submission, debarment & suspension etc. as well as TJU internal procedures; Completes subrecipient risk assessment in PeopleSoft; Manages the subrecipient sponsor table in Cayuse SP and PeopleSoft; Completes subcontract award information in Cayuse SP including tracking of subaward status, award amount, executed date & FFATA submission. Works with RACE & PI to resolve issues with missing documentation or issues with subaward negotiations; Works with RACE & ORA Postaward to ensure internal processes are complete for unbudgeted subawards or amendments 	<ul style="list-style-type: none"> Provides Subcontract Manager with applicable documentation as required such as revised subcontract budgets, scope of work, etc.; Works with PI to Complete internal subcontract documents (Subaward Request Form, Subrecipient Commitment Form, Subcontract versus Contractor checklist; Reviews subcontract agreement with PI before ORA issues agreements for signature to confirm reporting requirements and award amount; Approves Ascent Requisitions for applicable purchase orders 	<ul style="list-style-type: none"> Completes Subrecipient versus Contractor checklist; Approves subrecipient award amount and scope of work; Informs RACE and ORA of performance issues; Approves Subaward Request Form when adding unbudgeted subrecipients or requesting an amendment to an existing agreement; Works with collaborating PI to ensure compliance with applicable regulations (IACUC, IRB, FCOI); Works with RACE & ORA to resolve issues as the arise in the subcontract negotiation process

Process	ORA Responsibilities	RACE Responsibilities	PI/ Department Responsibilities
	<p>requested outside of Cayuse SP.</p> <ul style="list-style-type: none"> Approves Ascent requisitions to create applicable purchase orders. 		
Award Modifications (Spans both pre- and post-award)	<ul style="list-style-type: none"> Update Cayuse SP and route documents to post-award for account update Review UPAS for accuracy and appropriate backup documentation Verify there is an approved Cayuse SP record and check for appropriate regulatory documents Approve request and updated Cayuse SP record, notify post-award if action required 	<ul style="list-style-type: none"> Identifies need for award modification that requires ORA or Sponsor prior approval Completes internally required forms (e.g., UPAS, Cayuse SP) In collaboration with PI, drafts letter of request to the Sponsor (if applicable) Forwards required forms to ORA for review, if applicable 	<ul style="list-style-type: none"> PI and Senior Administrator approves UPAS (for advance accounts, pre-award costs, and cost sharing) as needed
Monthly Budget Reconciliation	<ul style="list-style-type: none"> Utilizes monthly financial reports to identify and pursue resolution for accounts that have expired and accounts with cash deficits. Special attention is paid to federal accounts that remain open > 90 days from the termination date Available for monthly grant review with RACE staff Processes cost transfers to remove deficit, or remove unallowable expenses Prepares metrics for management review 	<ul style="list-style-type: none"> Monitors spend patterns on sponsored accounts by reviewing data from the general ledger on a monthly basis and updating PI on balance and burn rate Documents data into RACE internal spreadsheet in order to make accurate projections for each grant and PI Submits Cost Transfers or requests a cost transfer from ORA for deficit removal or to remove unallowable expenses 	<ul style="list-style-type: none"> Department manages non-sponsored department accounts PI meets with RACE Grants Administrator on a monthly basis (at a minimum) to review grant accounts and pending submissions Department Administrator may attend monthly meetings if desired
Salary Distribution	<ul style="list-style-type: none"> Performs review and approval of all OSDs affecting a sponsored project Responsible for the "auto off" process, which stops salary from posting to the grant automatically after the authorized spending period has ended. Responsible for the Effort Confirmation (EC) adjustment process. 	<ul style="list-style-type: none"> Completes OSD (Online Salary Distribution) Form for salary on 080/ 081 accounts Obtains approval for salary distribution from the PI and Department Administrator 	<ul style="list-style-type: none"> Department Administrator approves OSD (if salary is hitting non-research accounts) Department Administrator initiates PAR/ PAF/ SFRAR HR Forms

Process	ORA Responsibilities	RACE Responsibilities	PI/ Department Responsibilities
Effort Reporting	<ul style="list-style-type: none"> Maintains the electronic effort system Ensures that reports are loaded according to schedule and monitors each deadline for 100% compliance 	<ul style="list-style-type: none"> Reviews all effort reports to ensure accuracy in a timely fashion Notifies Certifier once reports have been reviewed 	<ul style="list-style-type: none"> Approved Certifier – Certifies Effort Reports on time
Cost Transfers	<ul style="list-style-type: none"> Performs review and approval of all cost transfers Maintains data related to cost transfers (number, late, etc...) Initiates/processes cost transfers in accordance with the TJU costing policy (to remove an unallowable cost, deficit, or any transaction required to close an account or match a final report). 	<ul style="list-style-type: none"> Reviews expenses on sponsored accounts on a monthly basis and identifies expenses that must be transferred in accordance with the Sponsor, ORA, and TJU policies Prepares Cost Transfer form and completes > 90 day justification, if necessary Routes Cost Transfer form for approval 	<ul style="list-style-type: none"> Receives cost transfers that credit Department accounts for information purposes only Department Administrator approves cost transfers that debit Department accounts PI approves all cost transfers on sponsored accounts
Payment of Subcontract Invoices	<ul style="list-style-type: none"> Reviews all invoices for subawards. Approves, rejects or modifies invoices as appropriate. Obtains revised invoices, if applicable. Ensures proper allocation to grant account (i.e., invoice was keyed in AP, appropriate F&A was charged, posted to correct grant account). Updates RACE invoice tracking log Oversees the quarterly PI certification process for active subawards. Follows up on payment inquiries and missing invoices for subawards Obtains PI approval for final invoices 	<ul style="list-style-type: none"> Notifies ORA of subcontractors who are not submitting invoices in a timely manner Maintains record of all invoices submitted. Confirms accurate posting of invoices submitted to A/P for processing; Reviews subrecipient spending patterns with PI Informs ORA of subrecipient performance issues or missing invoices 	<ul style="list-style-type: none"> PI approves subcontract invoices for payment if desired (ORA policy does not require a PI approval, with exception of final invoices, under fixed price agreements & patient-related invoices. PI notifies RACE Grants Administrator and ORA should there be an issue with the work being completed by a subcontractor

Process	ORA Responsibilities	RACE Responsibilities	PI/ Department Responsibilities
Purchasing	<ul style="list-style-type: none"> Reviews and approves transactions as defined in the ORA signing authority document (See Appendix V). 	<ul style="list-style-type: none"> Completes purchase for PI or PI's designee (if requested) Retains documentation related to purchases on sponsored projects Approves purchases on sponsored projects in Ascent and in Payment Net 	<ul style="list-style-type: none"> PI or PI's designee identifies need for purchase Completes purchasing request form (if utilizing RACE purchasing capability) Forwards purchase confirmations and packing slips to RACE for auditable file
Closeout	<ul style="list-style-type: none"> Notifies PI and JCRI/RACE contact of pending termination and final reporting requirements Removes salaries from terminating grants via the " Auto off " process in the absence of OSDs Submits final invention reports to sponsor (after confirmation with OTT) as well as required equipment/property reports Pursues outstanding narrative reports Submits the Final RPPR in eRA Commons after error check and review of select data points Documents files with last active financial statement and all final reports with evidence of submission for audit purposes Closes account records in Cayuse SP and moves JeffShare file to closed folder. Purges files upon expiration of record retention period 	<ul style="list-style-type: none"> Reconcile all sponsored accounts in preparation for closeout Process OSDs required for grants that are ending Notify PI, purchasers, and senior department administrators that grant is ending at least 30 days prior to expiration Ensure final subcontract and consulting invoices are received Review final financial reports and invoices prior to submission to Sponsor Contact PI for technical report follow-up 	<ul style="list-style-type: none"> PI approves final financial reports PI completes all final technical reports required by Sponsor on time Department terminates employees (if applicable) once an award ends and processes paperwork as necessary

Contracting Services

Process	ORA Responsibilities	JCRI Responsibilities	PI/ Study Team
Pre-Award Clinical Trials Management		<ul style="list-style-type: none"> • Reviews and negotiates CDA • Obtains PI signature and executes agreement • Process and return CDA to sponsor • Receives study packet from JCRI/RACE or Sponsor 	<ul style="list-style-type: none"> • Execute CDA • Receive study packet from sponsor • For SKCC complete paperwork and feasibility for MDG and PRC review • Complete feasibility review for non-cancer studies • Provide final decision on pursuit of funding activity • Route study packet to JCRI
Contract Development and Execution (clinical and basic research contracts)	<ul style="list-style-type: none"> • Input, as needed, for JCRI negotiations 	<ul style="list-style-type: none"> • Receives sponsor CTA, r basic research, or other contract template unless master contract exists • Reviews/drafts subcontracts and contracts • Makes required revisions to contracts • Negotiates with Sponsor • Maintain contract status/tracking and metrics • Collaborates with legal, PI, IRB, IACUC as necessary • Adds final budget to contract • Upon receipt of regulatory and Cayuse approvals • Executes contracts as required • Input, as needed, for ORA grant negotiations 	<ul style="list-style-type: none"> • Input, as needed, for negotiations • Obtain regulatory approvals if applicable • Execute Contracts as required
Coverage Analysis	<ul style="list-style-type: none"> • Input as needed for CA development 	<ul style="list-style-type: none"> • Conduct QCT analysis in JeftTrial • Identifies items and procedures as research or standard of care 	<ul style="list-style-type: none"> • Input, as needed, for CA development • Assist with identification of items and procedures as research or standard of

Process	ORA Responsibilities	JCRI Responsibilities	PI/ Study Team
		<ul style="list-style-type: none"> • Enters billing determinations, and corresponding CPT codes into billing grid in JeffTrial; • Sends to PI/Study Team to review and approve coverage analysis • Submits appropriate IDE submission to Medicare (if device). • Release study calendar in JeffTrial • Review and release study calendar in Epic 	<p>care</p> <ul style="list-style-type: none"> • Final review and approval
Clinical Trial Budgets	<ul style="list-style-type: none"> • Input as needed for budget development 	<ul style="list-style-type: none"> • Develops internal study budget as a result of CA using charge master research rates, appropriate technical charges, applicable professional fees, relevant salary information, supplemental charges, and startup costs. • Interacts with PI/Study Team during budget development • Makes any adjustments as a result of CA Study Team • Converts internal budget to draft sponsor budget, includes margin on budgeted research rates • Negotiate budget and payment terms with sponsor and keeps PI/Study Team informed throughout Once approved, adds final budget to contract and Cayuse SP record and routes for approvals 	<ul style="list-style-type: none"> • Input, as needed, for budget development • Approve Cayuse SP record

Process	ORA Responsibilities	JCRI Responsibilities	PI/ Study Team
<p align="center">Clinical Trial Management Accounts Receivable</p>	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> Once ORA establishes account, activate clinical trial in Epic Maintain and update financial metrics on a continuous basis Prepare monthly financial reports for PI/Department Notifies PI/Study Team if contract should be amended due to accrual/financial implications Communicate any potential contract modifications to contracts team Renegotiate contract as Generate and send initial invoice to sponsor for all start-up fees Create VPT Ongoing monitoring of VPT to generate invoices as applicable Monitor SPAO monthly statements to identify all expenses charged to the account and invoice accordingly Generate and submit ongoing invoices to sponsor Follow up on outstanding invoices Receive payments, reconcile and deposit to appropriate account. Communicate to PI/Study Team/Department Administrator any 	<ul style="list-style-type: none"> Review monthly financial reports with JCRI Advises on changes in study status/accrual Notifies JCRI requesting contract/budget amendment Populate VPT with study subject information and any invoiceables (e.g. monitoring visits, SAEs, unscheduled events) Confirm milestones have been reached so JCRI can invoice sponsor

Process	ORA Responsibilities	JCRI Responsibilities	PI/ Study Team
		potential collection issues that may impact the department.	
Clinical Trial Management Accounts Payable	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> Review all study related bills in Epic to verify appropriate payer Review and approve IDTs for study related bills Review and approve Greenphire payments Create IDT request for Greenphire Monitor SPAO monthly statements to verify the appropriate expenses are charged to the account Review, approve and process all requisitions, RFPs and other bills from external entities 	<ul style="list-style-type: none"> Associate all study related visits in Epic Provide input on outstanding subject billing charges Submit request for Greenphire payment Enter requisitions into ASCENT Prepare RFPs
Salary Distribution / Personnel Review/ Purchasing	<ul style="list-style-type: none"> Performs review and approval of all OSD's affecting a sponsored project Responsible for the "auto off" process, which stops salary from posting to the grant automatically after the authorized spending period has ended. Responsible for the Effort Confirmation (EC) adjustment process 	<ul style="list-style-type: none"> Complete OSD and route for department approval Conduct monthly reviews of salary distribution charged to clinical trials to ensure accuracy Approve personnel coverage IDT's and forward to ORA Review and approve PARS & RFPs Approves Auto-Off salary distribution and ETO payouts upon employee termination 	<ul style="list-style-type: none"> Provide direction regarding salary distribution Department Administrator - Approves OSD Department Administrator – Initiates PAR/PAF HR Forms Process IDTs for personnel coverage
Cost Transfers	<ul style="list-style-type: none"> Performs review and approval of all cost transfer Maintains data related to cost transfers (number, late, etc...) Initiates/processes cost transfers in accordance with the TJU costing policy (to remove an unallowable cost, 	<ul style="list-style-type: none"> Review expenses on clinical trials on a monthly basis and identify expenses that must be transferred in accordance with the Sponsored Agreement, ORA, and TJU policies Prepare Cost Transfer form and completes > 90 day justification, if 	<ul style="list-style-type: none"> Receive cost transfers that credit Department accounts for information purposes only Department Administrator – approves cost transfer that debit Department accounts PI approves all cost transfers on clinical

Process	ORA Responsibilities	JCRI Responsibilities	PI/ Study Team
	deficit, or any transaction required to close an account or match a final report).	necessary <ul style="list-style-type: none"> Route Cost Transfer form for approval 	trials
Clinical Trial Closeout	<ul style="list-style-type: none"> Confirms disposition of residual balance in contract Reviews and approves JCRI/RACE closeout letter to ensure that all requirements have been met Alternatively, initiate closeout under authorization granted by Costing policy See standard closeout activities listed under post-award services. 	<ul style="list-style-type: none"> Reconcile account financials Confirm contract terms for closure Review A/R aging report to confirm all invoices sent and generate final invoice for unbilled activity Negotiate termination letter, as required Actively pursue financial closeout after notification of IRB closeout or study termination Receive final payment and confirm all expenses posted Review and approve closeout letter to ensure that all requirements have been met Initiate closeout under authorization granted by Costing policy Close account Change Epic status to Inactive 	<ul style="list-style-type: none"> Confirm completion of research activities Conduct site close-out activities including notification to IRB Provide IRB Closeout Letter to JCRI, Provide sponsor notification of study closure to JCRI Provide justification for residual greater than 25% and account to accept residual or cover deficit.
Annual Budget	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> Prepare draft ICR projections for next fiscal year Complete Hyperion template for departments, if requested 	<ul style="list-style-type: none"> Provide insight on accrual estimates Finalize ICR and enter into Hyperion Finalize personnel coverage and enter into Hyperion

JCRI does not provide support on the following matters related to sponsored awards:

- Maintaining faculty appointments
- Entering departmental annual budget information into Hyperion
- Travel arrangements or preparation of travel reimbursements
 - This includes travel related to conferences. Conference travel arrangements can include but are not limited to: registrations, abstracts, flight and hotel arrangements, and car rental.
- Coordination for department related meetings
 - This includes the coordination of catering, medical media services, audio visual preparations etc...

II. Roles and Responsibilities Matrix

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
Identify Funding Opportunities (Pre-Award)							
Meets with PI in order to gauge interest in Funding Opportunity Announcements			X				
Creates, collects, and disseminates funding opportunities campus-wide			X		X		
Identifies specific funding opportunities for faculty based on research area and key word search			X				
Corresponds with sponsors regarding specific funding opportunities	X						
Makes final decision on pursuit of funding opportunity	X	X					
Conducts periodic meeting with PI to discuss funding horizon and funded awards			X				
Maintains system access and system requirements for each potential sponsor					X		
Proposal preparation (Pre-Award)							
Manages planned applications for faculty via Cayuse SP working files			X	X			
Prepares and maintains Cayuse SP record for proposals due			X	X			
Prepares proposal - compiles administrative components			X	X			
Budget Development	X		X	X			
Prepares proposal - technical/scientific (including budget justification as it relates to the specific aims of the proposal)	X		X				
Approves proposed cost		X					

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
sharing							
Obtains documentation from proposed subcontractors			X	X			
Drafts Letter of Intent (administrative), if applicable			X				
Drafts Letter of Intent (scientific), if applicable	X						
Maintains copies of Biosketch and Current/Pending Support, documents in common files for use in future proposals	X		X				
Updates biosketches prior to proposal submission (including but not limited to: position title, education/training, personal statement, positions and honors, selected peer-reviewed publications, and research support)	X						
Completes, reviews, and routes proposal for approval			X	X			
Approves proposal	X	X			X		
Submits proposal to sponsor					X		
Award Reporting (Pre Award)							
Prepares all administrative components of Just in Time or other pre-award requests from the sponsor			X				
Verifies CITI certifications for human subject training is active			X		X (pre)		
Prepares protocol, if applicable	X						
Gathers regulatory approvals for JIT and Progress reports (IRB & IACUC)			X	X	X		
Prepares all administrative components of Progress			X				

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
Report submissions							
Verifies Carryforward Amount	x		x		x (post)		
Prepares all scientific components of Just in Time and Progress Report submissions (including ensuring the proper publications are linked in accordance with NIH Public Access Policy)	x						
Submits material (Just in Time documents/responses) to sponsor					x		
Award Acceptance (Pre-Award)							
Reviews award document and determines if a revised budget is required			x		x (pre)		
Reviews award terms and conditions and grant purchasing guidelines with the PI			x				
Gathers regulatory approvals for JIT and Progress reports (IRB & IACUC, Biohazards, etc.)			x				
Prepares protocol, if applicable	x						
Prepares awarded budget (if different from proposed budget)			x				
Approves awarded budget (if different from proposed budget)	x	x					
Reviews and confirms effort/salary cap/cost sharing			x	x			
Executes Subcontract				x	X (subs)		
Prepares coverage analysis				x			
Reviews and approves coverage analysis	x						
Accepts grant award on behalf of TJU					x		

Responsibility						
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO
Negotiates contract or award with sponsor on behalf of TJU				X	X	
Participates in negotiations as advisor	X		X	X		
Prepares and approves NIH and other federal non-grant/contracts				X	X	
Requests and monitors Advance Accounts			X			
Approves request for Advance Account		X			X	
Establishes account notifying all parties of account number					X	
Confirms selected data points in Cayuse SP and adds account number upon establishment					X	
Sets up award (or Advance) account in GL						X
Sets up award for transactional processes and systems (PeopleSoft/focus)						X
Enters approved cost sharing into O-drive database					X	
Completes Conflict of Interest Disclosures prior to expending funds on awarded grants	X					
Reviews to ensure COI is complete			X	X	X	
Award Modifications						
Identifies need for award modification	X		X	X	X	
Completes internally required forms (i.e. UPAS, Cayuse SP)			X	X		
Initiates request for No Cost Extension (NCE) or other award amendment			X	X		
Approves UPAS (for advance accounts, pre-award costs and cost sharing)		X			X	
Drafts letter of request to the sponsor			X	X		

Responsibility						
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO
Reviews required forms and submits request to sponsor				X	X	
Monthly Award Management (Post-Award)						
Monitors spend pattern compared to budget			X	X		
Documents data into JCRI/RACE internal spreadsheet in order to make accurate projections for each grant and PI			X	X		
Issues monthly grant management reports to JCRI/RACE administrators and departmental administrators						X
Reviews monthly grant award summary and prepares management reports (red zone, cash deficits, etc...)					X	
Pursues transactions necessary to close delinquent accounts (red zone)					X	
Reviews all red flag charges to award (such as federal express, office supplies, postage etc.)			X	X		
Obtains periodic confirmation of salary distributions from PI-exempt and key personnel			X	X		
Completes monthly reconciliation of grant accounts			X	X		
Resolves cost overruns on sponsored accounts via Cost Transfer			X	X		
Reviews status of grant accounts with PIs on a monthly basis			X	X		
Prepares projections/metrics sheet			X	X	X	
Collects, consolidates and distributes metric reports to					X	

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
management							
Analyzes Reserve						X	
Consolidates and copies monthly Postaward transaction data into JeffShare file					X		
Documents cost allocation methodologies (i.e., based on usage, FTE's)			X	X			
Annual Award Management (Post- Award)							
Provides award and projection data for Hyperion for departmental budgeting			X	X			
Enters data for annual budgeting process into Hyperion		X					
Initiates request for re-budgeting			X	X			
Approves re-budgeting request					X		
Provides fiscal year end metrics to management based on June books and transaction logs					X		
Salary Distribution							
Completes Online Salary Distribution Form for 080/081 accounts			X	X			
Obtains approval for salary distribution			X	X			
Approves PAR/ PAF/ SFRAR Human Resources Forms on sponsored accounts			X	X	X		
Approves salary distribution	X	X			X		
Initiates PAR/ PAF/ SFRAR Human Resources Forms		X					
Effort Reporting							
Triggers effort reports for review					X		

Responsibility						
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO
Reviews effort reports for accuracy			X	X		
Performs check of effort reports for all over-the-cap faculty					X	
Notifies certifiers once reports have been reviewed			X	X		
Certifies effort reports	X (Certifier)					
Processes Effort Confirmation (EC) adjustments					X	
Cost Transfers						
Prepares cost transfers and completes > 90 justification if necessary			X	X		
Prepares ORA-initiated cost transfers in accordance with costing policy					X	
Approves cost transfers	X	X			X	
Processes approved cost transfers						X
Review of animal charges			X			
Monthly/ Quarterly IDC Report: Sends Data to Department for F&A Split			X	X		
Monthly/ Quarterly IDC Report: Performs IDC Split		X				
Purchasing						
Approves all expenses (over a threshold or within certain categories)				X	X	
Approves PARs with 08* source distributions					X	
Initiates personnel changes (grant begin/end, prospective distribution changes)			X	X		
Initiates Purchase Order for PSA and Subrecipient agreements in Ascent			X	X		
Reviews and manages personnel changes (personnel		X				

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
hiring/terminations, unscheduled status/rate changes *no retroactive increases, for example)							
Tracks key personnel effort changes (RACE) and disclose to sponsor (ORA), if necessary			X	X	X		
Posts personnel charges to GL						X	
Posts fringe benefit adjustments to GL						X	
Applies cash received to the proper sponsored award				X		X	
Allocates grant salaries/expenses/purchases			X	X			
Approves salary/expenses/purchases					X		
Ensures purchases appropriate to award period			X	X			
Equipment purchasing, tracking, and safeguarding	X	X	X	X			
Approves equipment purchases					X		
Pursues sponsor-related collection issues as defined			X	X	X	X	
Posts PO encumbrance entries to GL						X	
Prepares and approve cash transfers			X	X	X	X	
Posts cash transfers to GL						X	
Applies unidentified deposits to clearing account; prepares and approves cash transfer when identified and applied to sponsored project						X	
Applies electronic funds						X	

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
Prepares and analyzes receivable/ advance balance sheet accounts						X	
Posts interest earnings when applicable						X	
Subrecipient monitoring							
Oversees subrecipient monitoring process					X		
Reviews invoices received prior to processing to A/P for payment (PI approval received for final invoices or under special circumstances)	X			X	X		
Addresses subrecipient questions regarding payment of invoices			X	X	X	X	
Approves Invoices for payment	X						
Addresses performance issues with subrecipient and report to RACE and central office immediately	X						
Follows up on missing invoices upon notification from RACE					X		
Closeout							
Prepares/Submits Invention statement					X		
Prepares final reconciliation/financial report/invoice				X		X	
Notifies appropriate personnel and PI that grant is ending			X	X	X		
Completes final reconciliation and closeout grant account			X	X			
Processes OSDs required for ending grants			X	X			
Performs "auto off" function to remove salary from grants that are closing (in the absence of a transaction)					X		

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
Approves final financial report/invoice	X		X	X			
Submits financial report/invoice				X		X	
Submits Final RPPR after review for errors and targeted data points					X		
Follows up with PI for delinquent technical reports, as needed/ Reviews to ensure all technical reports have been delivered			X	X	X		
Prepares and approves Relinquishing Statement (Race prepares, ORA approves)			X	X	X		
Reconciles cost sharing with residual balances					X		
Inactivates award on GL so no longer available for transactions						X	
Terminates employees if applicable, once award ends and processes paperwork		X					
Returns residual balance to sponsor, if required						X	
Compliance & Interim Financial Reporting							
Ensures PMS updates are correct per prior institution FFR and NOA						X	
Prepares external surveys					X		
Posts internal fees to GL						X	
Posts monthly F&A allocation						X	
Issues grant, PI, Department, School, and University statements and reports to all constituents						X	

Responsibility						
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO
Approves variations to full F&A rate as proposed by sponsors		X			X	
Disclosure for bond issues					X	
Submits annual CCR registration					X	
Completes annual disclosure in conjunction with TJU policy	X					
Works with TJU Research Administrative offices to ensure compliance	X	X	X	X	X	X
Check deposits related to sponsored accounts (receives check, completes form, sends to SPAO)			X	X		X
Other Activities						
Participates in continuing education	X		X	X	X	X
Coordinates all external audit requests					X	
Exhibits TJU and sponsor system proficiency			X	X	X	X
Responds to requests for information related to audits	X	X	X	X	X	X
Maintains current files (electronic) for use in audit requests			X	X	X	X
Ensures requisitions expensed and match exceptions addressed			X	X		
Maintains roles and users in sponsor systems					X	
Works with PI and sponsor to expedite transfer of award; confirm start date of employment			X	X	X	
Rate/ fee development, negotiation, and application					X	X
Posts TJU/H Subrecipient activity						X

Responsibility							
Role	PI	College/ School/ Dept./ Other	RACE	JCRI	ORA	SPAO	
Enacts related transactions; provides related management reports					X	X	
Performs after the fact review to ensure research incentive bonuses and coding is correct					X		
Documents circumstances requiring JeffTemps and Work Study related to grants			X	X			
Approves requisitions			X	X	X		
Documents and executes Professional Service Agreements				X	X		
Approves and retains support for P-card charges		X	X	X			
Prepares employee reimbursement report		X					
Approve employee reimbursement report on sponsored accounts			X	X	X		
Prepare final equipment report					X		
Provides PI- centric content for website			X	X			
Ensures regulatory/policy updates available to all			X	X	X		
Develops reports/queries as needed			X	X	X	X	
Prepares Travel Reimbursement forms	X	X					
Approves Travel Reimbursement on sponsored accounts			X	X	X		

III. Clinical Roles & Responsibilities Matrix

Responsibility							
Role	PI / Study Team	Department	RACE	JCRI	ORA	SPAO	
Pre-Award							
Receives study opportunity from	X			X			

<u>Responsibility</u>						
Role	PI / Study Team	Department	RACE	JCRI	ORA	SPAO
sponsor						
Receives, negotiates, and processes CDA				X		
PI signature	X			X		
Process CDA and return to sponsor				X		
Receives study packet from sponsor	X			X		
If cancer trial, MDG/ PRC review	X					
If not cancer trial, feasibility completed, prepare IRB submission, and obtain signatures (sends copy to JCRI)	X					
Submitted to IRB	X					
Prepare and maintain Cayuse SP record			X	X		
Contract, budget review and negotiation	X		X	X		
Enter final budget into Cayuse SP			X	X		
Review budget and send out for approval	X	X	X	X		
Confirm selected Cayuse data points and add account number upon establishment					X	
Finalize Cayuse SP after sponsor negotiation complete			X	X		
<u>Contracts</u>						
Receives study packet from sponsor	X					
For research determined as feasible, receives the CTA				X		
Begins review / drafting of contract. Occurs in parallel with the CA and budget processes				X		
Reviews contract language and terms and makes necessary revisions. Contract is reviewed for research related injury language consistent with IRB consent. Works with legal and may include PI, JCRI CRA and RACE GA as necessary				X		
Contract negotiation with sponsor which may include interaction with PI, Departments, IRB, JCRI CRA and				X		

<u>Responsibility</u>						
Role	PI / Study Team	Department	RACE	JCRI	ORA	SPAO
RACE						
Add final (negotiated) budget to contract				X		
Obtains regulatory approvals	X		X	X		
Executes contract				X	X	
ORA establishes study account. SPAO sets up account in GL and JCRI notifies billing staff.					X	X
Communicates with PI/study team & JCRI providing account information				X	X	
<u>Coverage Analysis</u>						
Receives study packet from sponsor	X					
Receives study materials and initiates CA				X		
Submits appropriate IDE submission to CA (if device study). Occurs after IRB approval.				X		
Answers QCT analysis questions (if not device study)				X		
Identifies items and procedures as research or standard of care	X			X		
Populate results / CA determinations into JeffTrial				X		
Review and approve CA	X					
<u>Budgets</u>						
Receives study packet from sponsor	X					
Develops internal study budget. Determines true cost utilizing charge master research rates, appropriate technical charges, applicable professional fees, relevant salary information, supplemental charges, and start-up costs. Interacts with study team during budget development	X		X	X		
Populates budget with patient care, personnel, fixed, and variable costs			X	X		
Converts internal budget to draft sponsor budget. Converts pricing to include margin on budgeted research rates			X	X		
Negotiates with sponsor to finalize			X	X		

<u>Responsibility</u>						
Role	PI / Study Team	Department	RACE	JCRI	ORA	SPAO
budget terms						
Add final budget to contract			X	X		
<u>Invoicing</u>						
Initial invoice for start-up fees				X		
Patient data entered by research coordinator into VPT	X					
Reviews study calendars and milestones				X		
Select milestones and invoiceables to add to invoice				X		
Generate invoice				X		
Export invoice and send to sponsor (posts and tracks A/R)				X		
Receives start-up fees				X		
Receive payment for sponsor				X		
If needed, confirms payment is for specific protocol	X			X		
Deposit payment into appropriate account on Deposit Upload Sheet				X		
Enter payment information and post to study account						X
Reconcile payments				X		
<u>Account Reconciliation</u>						
Populates study calendar with study subject information. Monitoring visits (any invoiceables) communicate to JCRI	X			X		
Accesses share drive to review study calendars				X		
Reviews study subject data against finances				X		
Reviews JeffTrials to identify all IRB reviews requiring invoice to sponsor				X		
Reviews accrual/study performance for financial implications				X		
Follows up on invoices to sponsors				X		
Monitors receipt of payments. Establishes timeline to communicate with Dept. and ORA on communicating outstanding payments				X		
Prepares update reports for PI / institution				X		

<u>Responsibility</u>						
Role	PI / Study Team	Department	RACE	JCRI	ORA	SPAO
If required, renegotiates contract with sponsor				X		
<u>Close-Out</u>						
Completion of research activities	X					
Close-out study financials			X	X		
IRB notification of study closure	X					
Monitors IRB terminations to ensure timely closeout				X	X	
Prepare for close-out visit	X					
Confirms contract terms for closure			X	X		
Conducts site close-out activities	X					
Final letter / communication from sponsor	X					
Generate final invoice for all unbilled activity				X		
Receives final payments from sponsor and reconciles account				X		
Confirms all expenses posted				X		
Manage deficits / cost transfers				X		
Confirm all payments received. Reviews A/R aging report, confirms all invoices sent, confirms payments posted correctly				X		
Close study account. Allocate residuals and cover deficits				X		
Evaluate study outcome. Financial analysis (residual vs deficit) and reason for study closure	X			X		
Approves close-out					X	
Performs ORA-initiated closeout, as needed					X	
Moves residual balance to designated fund or process cost transfer						X
Obtains necessary signatures				X		
Inactivate account in GL						X
Confirm close-out complete				X	X	

IV. Pre-Award Proposal Submission Standards

In support of the University's research mission, the Office of Research Administration is committed to providing quality service to the research faculty and fellows and to our campus colleagues by ensuring that applications for external funding are reviewed for compliance with all relevant policies of the institution and the policies and guidelines of the sponsoring agency. In order to fulfill this important obligation, ORA requires enough time to review proposal documents and provide guidance and feedback (as needed) to RACE/JCRI and the PI, review edits, and approve the applications for paper or electronic submission prior to the sponsor deadlines.

ORA requires the full administrative components of a proposal be submitted 5 business days prior to the sponsor's deadline. The scientific components are due 3 business days prior to the sponsor's deadline. The full lists of administrative vs. scientific requirements are outlined below:

Administrative (due 5 business days in advance of the sponsor deadline)	Scientific (due 3 business days in advance of the sponsor's deadline)
Approved Cayuse SP record	Bibliography & References Cited
Cost Share documentation	Introduction to Application Project Summary/Abstract (final) Project Narrative (final)
SF424 Tab 1 and 2	Specific Aims
RR Performance Sites	Research Strategy
Project Summary/Abstract (draft)	Progress Report Publication List
Project Narrative (draft)	Human Subjects Sections
Facilities & Other Resources	Vertebrate Animals
Equipment	Inclusion Enrollment Report
Biographical Sketch (current forms & format)	Appendices Authentication of Key Biological and/or Chemical Resources
Current & Completed Other Support (NIH past 3 yrs. / DOD past 5 yrs.)	Bibliography & References Cited
Budget	Introduction to Application Project Summary/Abstract (final) Project Narrative (final)
Budget Justification	Specific Aims
Subaward Documentation / Subrecipient commitment Form/Checklist to Determine Subrecipient or Contractor Classification	Research Strategy
PHS 398 Cover Page Supplement tab 1 and 2	Progress Report Publication List
Multiple PD/PI Leadership Plan	Human Subjects Sections
Letters of Support	Vertebrate Animals
Resource Sharing Plan	Inclusion Enrollment Report
PHS 398 Checklist	Appendices Authentication of Key Biological and/or Chemical Resources
PHS 398 Cover Letter	Bibliography & References Cited

ORA's review criteria for proposal submissions will differentiate between levels of review based on submission timeframe in which ORA receives the complete proposal package.*

1. Proposals received 5 business days in advance of the sponsor deadline will receive a **full** proposal review for the following administrative items:
 - a. Fatal System Errors
 - b. Follows Sponsor Guidelines
 - c. Unallowable Costs (i.e., Administrative salaries, food, alcohol, etc..)
 - d. Personnel/Consultant Costs (i.e., ensuring these are charged appropriately)
 - e. Indirect Costs (correct rate and correct exclusions)
 - f. Subawards
 - i. Subawards are categorized appropriately as subs vs. purchased services
 - ii. Subaward commitment forms are present
 - iii. Subrecipient or Contractor Classification form is present
 - iv. Visual Compliance: Debarment/Exclusion status check
 - g. Costs are categorized appropriately
 - h. Budget justification matches budget
 - i. Cost Sharing is listed appropriately (if included)
 - j. All internal documents are present and signed/approved
 - i. Cayuse SP (fully approved, with status "Pending ORA Review")
 - ii. PI Signature
 - iii. Assignment of Invention (online form)
 - iv. COI (online form)
 - v. Human/Animal Approval Dates
 - vi. Problematic Terms and Conditions

2. Proposals received less than 5 business days in advance of the sponsor deadline will receive a **partial** review for institutional compliance issues only:
 - a. Fatal System Errors that would cause an unsuccessful proposal submission
 - b. All internal documents are present and signed/approved
 - i. Cayuse SP (fully approved, with status "Pending ORA Review")
 - ii. PI Signature
 - iii. Assignment of Invention (online form)
 - iv. COI (online form)
 - v. Human/Animal Approval Dates
 - vi. Problematic Terms and Conditions
 - c. Proposal has received all required approvals
 - d. Human/Animal approval dates are correct or noted as "Pending" on the application
 - e. All subaward forms are present and signed
 - f. Unallowable Costs (i.e., Administrative salaries, food, alcohol, etc..) are not present

ORA makes every effort to review and submit proposals received after the policy guidelines, but cannot guarantee that such proposals will be adequately reviewed or submitted by the sponsor deadline. Please note that online submission systems such as Grants.gov require validations that often take up to 24 hours before providing receipt of confirmation by the sponsoring agency for review. **Complete packages received within the established ORA**

deadline (5 business days for administrative components and 3 business days for scientific components) will be submitted to the sponsor by 1 pm on the deadline day (if not sooner).

V. ORA Signature Authority

ORA review and approval is required for the following transactions whenever any grant account is affected (business units 080 through 086).

- On Line Salary Distribution Requests (OSD's)
- Position Authorization Requests (PAR's)
- Salaried Faculty Recruitment Authorization Requests (SFRAR's)
- Personnel Action Forms (PAF's) with the exception of tax and address changes
- Off-cycle payroll check requests
- Jeff Temp requests
- Cost Transfers
- Cash Transfers
- Graduate School requests to charge stipend, health insurance and/or tuition
- Construction Project Summary Sheets
- Interdepartmental Transactions (IDT's) exceeding \$5,000. In addition, ORA must approve *all* TJUH/JUP payments, regardless of the dollar amount.
- All personal reimbursements, including travel and petty cash, regardless of the dollar amount.
- ASCENT requests exceeding \$5,000. In addition, ORA must approve *all* subcontracts, capital requests and professional service (consulting) agreements, regardless of the dollar amount.
- Request for Payment (RFP) exceeding \$5,000. In addition, ORA must approve *all* subcontracts, capital payments, honorariums and consulting payments, regardless of the dollar amount.