Research Administration Services

Roles & Responsibilities

For Clinical Trial & Clinical Research – Version 3.2

(EXCLUDES PATIENT FACING ACTIVITIES AND STANDARD OF CARE BILLING ACTIVITIES)

Category	PI/Study Staff*	Department	RAS Unit	School/Unit	ORA Offices	Relevant SOP
Protocol Development	• Obtain Clinical Trial Protocol and budget (if available) from sponsor • Obtain draft Clinical Trial agreement from sponsor • Notify RAS unit of intent to submit		• Maintain list of Clinical Trials in process		• Sign non-disclosure agreement *(OSP)*	• 1001: Notification of Intent to Submit
Obtain Compliance Approvals	*Please note – not all may be necessary for each study* • Complete EHC Quality Checklist (Radiology, EML, Nursing, IDS) & Key Points Summary • If necessary, obtain relevant affinity group approval • Obtain EHSO Approvals • Complete IFIRR forms (COI) • Obtain approval for use of CIN resources • Obtain IRB approval • Obtain VA R&D approval • Obtain GROC approval • Complete Form FDA 1572 • [For Winship Studies only] – Obtain Winship CTRC approval – Enter new project		• Navigate and Monitor Progress • Enter new project into eCOI [Except for Winship studies]			• 1002:Research Proposal Application Process – Non-Complex • 1003: Complex Award Management – Pre - Award

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*For Winship Cancer Institute trials, some of these may be regulatory staff responsibilities; For studies at CHOA, some of these responsibilities may be CHOA responsibilities

Activities highlighted in yellow are activities responsibilities that will be moved to RAS units after training has occurred

Category	PI/Study Staff*	Department	RAS Unit	School/Unit	ORA Offices	Relevant SOP
Enter proposal/ protocol into EPEX *(note: this process may occur before all compliance approvals are obtained)*			• Compile all relevant Clinical Trial/protocol elements from PI/coordinator • Enter relevant documents into EPEX • Ensure information entered into EPEX is complete and accurate, including overhead • Submit for routing in EPEX			• 1002 • 1003
EPEX Protocol Routing	• Certify protocol in EPEX	• Review and approve protocol in EPEX for the following, if applicable: – Dept cost share commitments (including salary cost share) – Dept space commitments – Type of research and key personnel performing research	• Monitor protocol progress through EPEX approval process	• Approve budget & protocol in EPEX, if required (note, if there are Emory Billables, this either is not required or happens after OCR approves & develops the budget)	• [OCR]: Approve study in EPEX & route to OSP if a non-federal study (unless certain EPEX workflow responses trigger review by School)	• 1002 • 1003

Category	PI/Study Staff*	Department	RAS Unit	School/Unit	ORA Offices	Relevant SOP
PRA and Budget Development	• Provide inputs for budget (protocol, procedures & notify Purchasing if EHC device). • Determine how to operationalize the study procedures. • If federal study awarded JIT, submit to OCR for PRA if EHC billables or submit ERMS Activation Form to OCR if no EHC billables.	• Approve any cost-sharing	IF CHOA BILLABLES or FEDERAL STUDY: *(please note, these activities should occur before protocol routing)* • Submit IDS budget request • Develop Draft budget • Choose Cost Option Language for CHOA billables & share with OSP/IRB (OCR will provide cost option to OSP & IRB for EHC billables). FOR INVESTIGATOR INITIATED STUDIES: • Request LOI budget from OCR (for Industry Sponsors ONLY)	• Review final budget • Approve any cost-sharing	IF EMORY BILLABLES: • [OCR]: Develop PRA IF NON-FEDERAL BUDGET *(excluding CHOA budgets)*: • [OCR]: Develop draft budget • [OCR]: Submit IDS budget request • [OCR]: Negotiate budget with sponsor (keep PI informed, as necessary) • [OCR]: Incorporate Budget into Contract (work with OSP) • [OCR]: Set up ERMS budget • [OCR]: Update OCR Study Status Tracking System with progress of PRA & budget IF EMORY BILLABLES OR NON-FEDERAL BUDGET: • {[OCR]: Choose Cost Option Language for Emory billables & share with OSP/IRB • [OCR]: Notify EHC if devices are being used at Emory site FOR ALL STUDIES (Federal & Non-Federal): • [OCR]: Set up ERMS study & placement groups FOR PI INITIATED STUDIES *(excluding CHOA budgets)*: • [OCR]: Prepare LOI budget (for Industry Sponsors ONLY)	• To Be Integrated into SOP #1004

Category	PI/Study Staff*	Department	RAS Unit	School/Unit	ORA Offices	Relevant SOP
Contract Negotiations [SAME AS GRANTS AND CONTRACTS]			• Monitor progress of contract negotiations		• [OSP]: Negotiate Contract with Sponsor • [OSP]: Negotiate and Approve Subject Injury Language and notify IRB *(work with PI, as necessary)* • [OSP]: Update eCTS (Contract Tracking System) with progress of contract • [OSP]: Sign Clinical Trial Agreement on behalf of university • [OSP]: Notify RAS unit when contract has been signed	• 1002
Award Set-up [SAME AS GRANTS AND CONTRACTS]		• Collaborate with RAS unit when moving personnel off department accounts	• Send eNOA to PI, Co-PIs and their respective RAS units, and OGCA • Set-up payroll distributions; collaborate with department if moving personnel off department accounts • Fill out award cover sheet • Meet with PI to ensure sponsor deliverables and restrictions are understood		• [OSP/DMG]: Set-up award in Compass and generate SmartKey • [DMG]: Issue eNOA and upload into ComSquared and I-drive • [OGCA]: Activate bill plan, set up Invoicing and FFR milestones • [OGCA]: If applicable, ensure cost sharing project has been assigned • [OGCA]: If applicable, set up program income account	• 2001: Complex Award Management Post Award • 2003: Award Set up Process • 2004: Payroll distribution Set- up

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Establishing Subawards/ Subcontracts [SAME AS GRANTS AND CONTRACTS]	• Gather and review sub documentation, including budgets and statement of work • Define sub deliverables and milestones		• Obtain sub documentation from PI • Submit request for subaward/subcontract in Sub Request System • Monitor progress of sub negotiations		• [OSP]: Negotiate and sign sub with sponsor • [OSP]: Create PO in Emory Express • [OSP]: Notify RAS unit when sub has been fully executed	• 2005: Requesting a Subaward or Subcontract
Study Start-up	• Develop Delegation of Authority Log • [Winship Studies Only] – Complete Winship Checklist to Open Protocol – Upload study data to OnCore • Enter research subjects in ERMS on same day as consented	• Ensure study staff have proper credentials and training			• [OCR]: Enter study level documents into PowerTrials if CT or Emory site after eNOA • [OCR]: Flag research subjects & enter patient level documents into EeMR on same day as ERMS entry if clinical trial & Emory site (except if deemed sensitive by IRB) • [OCR]: Provide mandatory clinical trials training & BLS for all study staff • [OCR]: Facilitate ClinicalTrials.gov entry & problem resolution for Emory sponsored clinical trials & enter NCT# into ERMS for all Emory studies if ACT or Phase 1	• N/A

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Conduct Clinical Trial and Manage Expenses	• Conduct clinical trial • Hire any staff needed to conduct clinical trial • Purchase supplies and equipment • Provide guidance to RAS on award expenses or projections, as necessary • Ensure regulatory compliance certifications are up to date • Enter patient visit information into ERMS and sponsor systems (if applicable)	• Collaborate with RAS Units on movement of any expenses to department accounts • Process Travel & Expense reimbursements	• Reconcile expenditures and create projections on award expenses every 60 days; ensure expenditures do not exceed budget – Ensuring expenses are allowable – Confirm with PI any expenses that do not look like they belong on the award – Submit any cost transfers, retroactive salary transfers, and journal entries – File CAS exceptions • Send reports on reconciliation and projections to PI • Approve Emory Express purchases • Coordinate updating SmartKeys with Recharge centers • Clear suspense accounts for sponsored projects only	• Approve CAS exceptions	• [OGCA]: Enter paper retroactive salary transfers (RSTs)	• 2001: Complex Award Management Post Award • 2007: Projections and Forecasting • 2008: Reconciling Expenditures • 2009: Cost Transfers • 2014: CAS Exceptions

Category	PI/Study Staff*	Department	RAS Unit	School/Unit	ORA Offices	Relevant SOP
Sponsor Invoicing			• If OCR is being utilized for invoicing: – Coordinate with OCR and coordinators to ensure invoices are sent on time • If RAS unit is completing invoicing: – Develop invoice and send to sponsor – Inform OGCA of proper account to apply cash		• If OCR is being utilized for Invoicing: – [OCR]: Send invoice to sponsor per CTA & verify grant charges per PRA. Facilitate charge corrections w/CTBD. – [OCR]: Receive checks from sponsor & send to OGCA w/in 24hrs – [OCR]: Inform OGCA of proper account to apply cash – [OGCA]: Apply cash to account – [OCR]: Pay internal & external monies owed for services performed including patient stipends & travel reimbursement • If RAS unit is completing invoicing: – [OGCA]: Receive checks from sponsor – [OGCA]: Apply cash to account	• To Be Integrated into SOP 2010: Invoicing

Paying Subawardees/ Subcontractors [SAME AS GRANTS AND CONTRACTS]	• Confirm subawardees/ subcontractors have completed work before payment is sent		• Receive notification of invoice from Emory Express • Obtain confirmation from PIs that work has been completed and approve payment of invoice in Emory Express • Manage (with Payment Services) disputes regarding subaward invoicing and payments		• [Payment Services]: Receive invoices from subawardees/ subcontractors; request approval for payment from RAS units • [Payment Services]: Pay invoices • If OCR is being utilized for Invoicing: – [OCR]: Pay internal & external monies owed for services performed including patient stipends & travel reimbursement	• 2006: Paying subawards and subcontracts
Category	**PI/Study Staff***	**Department**	**RAS Unit**	**School/Unit**	**ORA Offices**	**Relevant SOP**
No Cost Extension (NCE)	• Complete justification for NCE • [If Sponsor approval is required]: Draft letters to sponsors for NCE request		• Assist in gathering documentation needed (if any) for NCE • Submit requests for NCE to OSP • Inform PI and Co-PIs if NCE has been received		• [OSP] If granted authority, approve NCE • [OSP] If not granted authority, submit NCE requests to sponsor • [DMG]:Upon approval, update Compass with new end date and prepare new eNOA	• 2013: No Cost Extension
Amendments (language changes only)	• Gather amendment and other related documents and submit to RAS unit		• Submit amendment and related documents to OSP via OSP listserv		• [OSP]: Negotiate change to CTA with sponsor and execute new contract • [OSP]: Notify RAS unit when contract has been signed	•

Award Close-out **[SAME AS GRANTS AND CONTRACTS]**	• Notify RAS, IRB & OCR if a study is terminating • Review and approve final reportable expenses • Prepare invention statement, if applicable • Prepare non-financial reports • Maintain non-financial records	• Approve transfer of residual balances or deficits • Approve movement of salary to department accounts from sponsored projects	• Reconcile expenses; review F&A, cost share, and program income; determine final reportable expenses; confirm final numbers with PI • Notify feeder systems of end of award • Clear encumbrances • Adjust payroll distributions • Prepare Final FFR/Final Invoice and submit to OGCA • Determine if deficit or residual balance and work with dept/school to transfer • For Compass close-out, ensure ensuring budget = General Ledger = final expenditures; notify OGCA when SmartKey should be inactivated	• Approve transfer of residual balances or deficits	• [OGCA]: Review, approve, & submit Final FFR/Final Invoice to sponsor • [OGCA]: If necessary, return funds to sponsor • [OGCA]: Ensure all cash has been collected & posted to award; clear any outstanding A/R • [OGCA]: Inactivate smartkey • [OGCA]: Retain award financial records • [OCR]: Off-study subjects in PowerTrials & close study in ERMS & PowerTrials. • If OCR utilized for Invoicing: – [OCR]: Reconcile study account to determine all monies owed are received per CTA. Ensure balances in Compass & Invoicing database match.	• 2021: Prepare Final FFR/Final Invoice • 2022: Close-out Award