University of Florida Health Science Center/Jacksonville Research Manual

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Contents

INTRODUCTION

The purpose of this research manual is to assist with research administration for all research activities conducted at University of Florida - Jacksonville, UF Health Jacksonville and UF Jacksonville Physicians, Inc (to be referred to as UF-Jax) and to understand the standard policies and procedures required for administering research studies at UF-Jax. UF-Jax encompasses the Downtown, Emerson and North campuses. The policies and procedures in this research manual encompass virtually all administrative aspects of preparing, conducting, and closing research projects. It also includes ready access to all of the forms and other required documentation as well as a wealth of other information, such as myUFL instruction and required training, links to fee schedules and contact information.

Our affiliated teaching hospital, UF Health, and our faculty practice plan, University of Florida Jacksonville Physicians, Inc. (UFJPI), play an essential role in the registering and billing procedures since both entities are responsible for recovering technical and professional fees respectively. UFJPI is a "not for profit" corporation that supports University of Florida. The combined efforts of both of these organizations as UF Health afford exceptional institutional support for the research enterprise of UF-Jax.

Office of Research Affairs

The Office for Research Affairs (ORA) is the UF Division of Sponsored Programs (DSP) office for UF-Jax. Information about DSP is available at http://dev.hscj.ufl.edu/research/researchaffairs.aspx . Please note, however, that details of some UF policies and procedures are different for UF-Jax and thus, it is important to consult this Research Manual or contact the ORA staff for clarification in case of an apparent conflict.

ORA is a service-oriented department offering assistance to faculty and staff at UF-Jax regarding research-related matters. ORA assists faculty, staff and residents in securing and administering outside support (as well as internal support such as the Dean's Fund Grants) for their instructional, research, and public service activities. ORA reviews and approves research grant proposals to ensure compliance with University of Florida and sponsor agency rules and regulations. ORA also serves as the contract reviewers and negotiators for all research contracts, no matter the funding agency. **Only the ORA Senior Assistant Dean has official signature authority for research agreements and grant applications related to research conducted at University of Florida, Jacksonville** (https://research.ufl.edu/dsp/award-negotiation-and-acceptance.html).

ORA regularly communicates with departmental research administrators through its UF Jacksonville Research ListServ, so if you wish to be added to that email distribution list, please send an email request to ORA@jax.ufl.edu. ORA also convenes monthly meetings for departmental research managers and coordinators to provide policy and procedure updates as well as a forum for discussing relevant research administration issues.

University of Florida ID (UFID)

When you are hired at UFJPI, you are assigned a UFID. This ID allows access to the required trainings and systems required for your position. If you do not know your UFID, you may contact Human Resources or ORA.

For assistance or questions, please call the ORA at 244-9478.

SECTION I: Resources

ORA Request Portal

The ORA Request Portal is an online tool designed for all faculty and staff to submit tailored requests for all research-related services. The Request Portal takes approximately five minutes to complete and establishes a systematic process that ensures project success through clear, documented communication with the ORA. Services provided by ORA through the ORA portal include:

- Additional education and training
- Assistance with obtaining research personnel
- Budget management and negotiation
- Contract management and negotiation (UFIRST)
- Human subjects research support (IRB)
- Ensuring compliance with UF, and sponsor agency rules and regulations
- Effort reporting
- Space allocation
- Study/protocol development
- Biostatistics
- Research analytics
- Biorepository
- Entrepreneurial support

ORA Request Portal: https://ufl.qualtrics.com/jfe/form/SV_3dvfjMe4Wd0qMgl

ORA Training Portal

The ORA training portal is an online tool designed to address the training needs for all research staff throughout campus. Simply complete the questionnaire and you will receive an email(s) with the required comprehensive training tailored to your role.

ORA Training Portal: ORA Training Portal

Institutional Review Board

Research projects to be conducted at UF-Jax require approval from one of the following Institutional Review Boards:

IRB-01

For all research that is not a sponsor-initiated, pharmaceutical industry sponsored clinical trial, the University of Florida Institutional Review Board (IRB-01) reviews and approves human subject research. **myIRB** is the electronic submission system that allows research investigators to submit their IRB protocols.
Link to IRB01: http://irb.ufl.edu/irb01/irb-01.html

IRB- 02

The Behavioral/NonMedical IRB (IRB02) is responsible for reviewing and monitoring a subset of the research with human subjects conducted at the University of Florida. This board reviews research studies that involve: behavioral observations/recordings, non-invasive physiological recordings, analysis of documents that were

previously gathered for non-research purposes, evaluation of behavioral/social interventions or manipulations, educational assessments, interviews, surveys, cognitive tests, and taste/food evaluations within FDA regulations.
myIRB is the electronic submission system that allows research investigators to submit their IRB protocols.
Link to IRB-02: http://irb.ufl.edu/irb02.html

myIRB
myIRB is the online submission platform for the University. **Registration is required**.

The Researcher Manual provides assistance with navigating myIRB.
(https://my.irb.ufl.edu/UFLIRB/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity[OID[AC482809EC03C442A46F2C8EEC4D75D3]]
Please note, the Gatorlink VPN connection is required to access when offsite. Any questions regarding the UF IRB submission process, please contact the ORA via the ORA Portal Request
(https://ufl.qualtrics.com/jfe/form/SV_3dvfjMe4Wd0qMgl).

WIRB
For all research projects at UF-Jax that are sponsor-initiated, pharmaceutical industry sponsored clinical trials, UF has contracted with the Western Institutional Review Board (WIRB) to review and approve human subject research. Detailed information regarding submissions for WIRB approval is available at:
http://irb.ufl.edu/irb-04-home-western-irb/submitnew.html
For more information regarding IRB, please see *Appendix A: IRB and HIPPA*.

IRB Ancillary Review - Financial Language Assessment (FLA)

Research Administration and Compliance (RAC) Review
Studies that involve human subjects and services (regardless of service location, sponsor, or payer) have to be evaluated by the ORA for billing compliance risk and Informed Consent financial language recommendations before IRB submission. There are two forms that are required to submit for FLA:

Division of Sponsored Research Informed Consent Financial Language Assessment (DSP-Jax FLA)
Consent Form Checklist

These forms are required for WIRB and IRB-01.

Forms are located at: F:\common\Research Studies\Office of Research Affairs (ORA)\IRB\RAC Review

UF IRB-01 –FLA process

https://rac.med.ufl.edu/preparation/irb/irb-01/
Upon submission of the IRB application, ORA will be notified that Ancillary Review is required for financial language assessment. At this time, ORA will request the completed DSP- Jax FLA Form and Consent Form checklist be sent to ora@jax.ufl.edu.

The DSP-JAX FLA form and Consent form checklist will be reviewed by ORA to ensure consistency with the clinical trial agreement. Upon approval, ORA will complete the RAC ancillary review in myIRB.

WIRB- FLA process

https://rac.med.ufl.edu/preparation/irb/irb-04/

Attach the completed DSP- Jax FLA Form and consent form to the UFIRST Agreement under "Supporting Agreement Documents".
Send a red-lined ICF including the applicable UF/WIRB ICF template language to Regina Leonard (ORA/DSP-Jax). The ICF cost and injury sections will be reviewed by ORA to ensure consistency with the Agreement. Upon approval, a signed DSP- Jax FLA Form will be returned to the department for upload into UFIRST.
Questions can be directed to Office of Research Affairs at ora@jax.ufl.edu.

HURRC Review

The Human Use of Radioisotopes and Radiation Committee (HURRC) must review all projects that involve the RESEARCH USE of DIAGNOSTIC X-RAYS, RADIOACTIVE MATERIALS, or THERAPEUTIC RADIATION, as well as all research submitted to WIRB (regardless of whether it involves radiation). Even a standard diagnostic test used more frequently than clinically indicated would constitute research with radiation. If HURRC review is required, you cannot begin the project until you have both IRB and HURRC approvals. If you have questions about HURRC review, additional information can be obtained at: http://www.ehs.ufl.edu/programs/rad/

Office of Clinical Research Review

If the research submitted is a clinical trial, it may need to be registered on clinicaltrials.gov. OCR – Gainesville will make this determination and notify the PI. See Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT): https://prsinfo.clinicaltrials.gov/ACT_Checlklist.pdf

Award Management (UFIRST)

The UFIRST Award Management system is the resource designed to manage all funded or potentially funded UF studies, proposals and agreements. UFIRST utilization is mandatory for the entry and routing, and allows transparent tracking throughout the lifecycle of the award.

PROPOSALS

For investigator-initiated grant funded studies (NIH, DOD, DOH, foundation and industry sponsored), UFIRST is initiated at proposal development and used throughout proposal submission, award negotiation, set up and management. More specifically, UFIRST functions include:

- Storing institutional proposal data
- Routing pre-submission proposals to external sponsors
- Federal Grant Applications electronic submission to Grants.gov
- Collecting sponsored and research-related agreement information
- Tracking negotiations on all sponsored and research-related agreements
- Collecting institutional award data
- Hosting Notices of Award
- Facilitating award management request tracking

Proposals entered into UFIRST must be completed and routed for signature a minimum of two days prior to application deadline. ***Please see policy***: https://research.ufl.edu/dsp/proposals/proposal-deadline-policy.html

Frequently used facts for proposal submission are available at:
https://research.ufl.edu/dsp/proposals/frequently-used-facts.html

Toolkits and training are available at https://learn-and-grow.hr.ufl.edu/toolkits-resource-center/financial-toolkits/grants/

Non Disclosure Agreements (NDA)

Non-Disclosure Agreements or Confidential Disclosure Agreements are legal contracts that prohibit someone from sharing information deemed confidential. They are usually required before an industry sponsor will share a protocol. The NDA/CDA is uploaded by dept. research personnel to UFIRST for review and negotiation. See Section II: Pre-Award.

Industry Sponsored Clinical Trial Agreements (CTA)

For industry initiated clinical trials, a proposal is not required. The CTA is uploaded by dept. research personnel to UFIRST for review and negotiation along with a signed copy of the Clinical Trial Checklist:
F:\common\Research Studies\Office of Research Affairs (ORA)\Forms.
See Section II: Pre-Award.

Effort Reporting

The most significant cost to sponsored programs is salaries, wages, and related fringe benefits, and ensuring proper management of these funds is a priority of the University of Florida. Department research personnel are required to verify PI effort on federally funded projects.

When a PI is awarded a federally funded grant and has a portion of their salary charged to the grant, please contact **ORA.**

For directives and procedures, please visit:
http://www.fa.ufl.edu/directive-categories/effort-certification/
http://www.fa.ufl.edu/directives/quick-facts-for-effort-coordinators/

Training in effort management and certification is required by University faculty and support staff engaged in sponsored activities. Both courses can be accessed in the University's online training system, through myUFL. Please visit: https://research.ufl.edu/dsp/award-management/fiscal-management/effort-reporting.html

EPIC

EPIC is the electronic medical record, scheduling, and billing system for UF Health. EPIC includes a research module, which is designed to assist researchers with research billing compliance by listing UF Studies that include-protocol required patient-based billable services, identifying what patients in the UF Health System are participating in these studies, and allowing research teams to review patient charges prior to claims submission to ensure that study funded services do not get billed to the study participants or their insurance.

The link below provides access to **RESEARCH TIPSHEETS and TRAINING INFORMATION:**
http://1b-esx-infonet.umc.ufl.edu/UFJP-epic-training/Documents/Forms/AllItems.aspx?RootFolder=%2FUFJP%2Depic%2Dtraining%2FDocuments%2FResearch%2FTipsheets&FolderCTID=0x01200075BD6B9383174743B2B4A59E1DB7F23C&View=%7B2A7797E9%2DC593%2D4575%2D9738%2D0116E1C0E2F8%7D

Forms and additional information may be accessed at:
F:\common\Research Studies\Office of Research Affairs (ORA)\EPIC

Types of Studies

For the purposes of this manual, we have categorized research by sponsor type.

Industry/Investigator initiated clinical trials

Industry sponsor funding comes from a private entity, such as a drug or device company, and functions through the oversight of a clinical trial agreement.

Investigator initiated funded projects

Investigator initiated grant/award funding is awarded to an institution, department, or investigator through a federal, state, local or non-profit entity to allow for participation in a study, develop a program or study, or implement a community-based project.

Investigator initiated non-funded

Unfunded research investigator initiated studies are research studies initiated and managed within a UFHSC/J department or division and do not receive financial support. Non-funded investigator initiated studies must be submitted and approved through the UF IRB system prior to activation.

The table below provides an overview of the 3 types of studies at both pre and post award stages:

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TABLE 1: Overview

	Industry/Investigator Initiated	**Investigator Funded Projects**	**Non-funded Projects**
Purpose	Advance clinical practice by participating in clinical trials	Investigator initiated research, most often in response to a program announcement/RFP	Collect pilot data; (may be required for residency/fellowship)
Protocol	Provided by sponsor, generally implemented at multiple sites	Prepared by PI and research team; experts in their field; most often in response to an announcement	Proposal prepared by PI and research team, experts in their field
IRB type and timing	WIRB, during CTA negotiations	IRB01, most often upon award	IRB01, before research begins (includes prep to do research)
Required forms (UFIRST)	Agreement (CDA/CTA) is entered into UFIRST for review, negotiation & execution by ORA	Proposal is entered into UFIRST; ORA reviews and submits to the funding agency	Not entered into UFIRST
Approval to start research	Full execution of CTA, budget and WIRB approval.	Upon award from funding source and IRB approval	IRB approval
Indirect cost	Please see UF F&A Rate Agreement: https://research.ufl.edu/wp-content/uploads/FA-Agreement.pdf	Please see UF F&A Rate Agreement: https://research.ufl.edu/wp-content/uploads/FA-Agreement.pdf	N/A
Indirect Cost Return	A portion of the IDC goes to the PI overhead account, a portion to the PI's Department, and a portion to the University	A portion of the IDC goes to the PI overhead account, a portion to the PI's Department, and a portion to the University.	N/A
Invoicing/Payments	Research dept. invoices the sponsor in **accordance with** terms and conditions of CTA; non-refundable start-up costs invoiced upon full execution of CTA; reimbursement should remain current with expenditures throughout the life of the study	The funding agency is invoiced by UF C&G per scope of work & agreement; reimbursement should remain current with expenditures throughout the life of the stud	N/A
Effort Reporting	Not applicable.	Effort is reported & certified fall, spring and summer based on actual effort on project.	Effort on unfunded research should be listed and certified as part of faculty assignment.

Close out	IRB closeout initiates post award audit to ensure compliance and all invoices are paid in full; funding received but not spent is deposited into a residual account in accordance with dept. policy	In accordance with sponsor guidelines; unspent funds often returned	IRB closeout
Staffing		UF Employees who are key personnel are listed in the proposal and the agreement. Staff who are not yet hired but will be UF employees are listed as TBD. UFJPI/UF Health or other non-UF key personnel or staff are listed as "other direct costs."	
Recruitment of participants	Defined in CTA	A set number of participants as identified in Proposal/Agreement	Up to a set number of participants as defined in the protocol.
Human Subject Payment	Completed through the UF HSP	Completed through the UF HSP	Completed through the UF HSP, if applicable
Reallocation of budget		Generally requires funders approval, including to add or change key personnel	N/A

Section II: Pre-Award

Industry/Investigator-Initiated Clinical Trials

For general background information about research administration for clinical trials, go to *Appendix B Research Administration Basics for Clinical Trials*.

Pre-Award procedures are defined as the steps involved prior to the implementation of clinical trial. Pre-award procedures for pharmaceutical industry sponsored clinical trials generally involve the following components:

Feasibility questionnaire

The Feasibility questionnaire (FQ) is the set of questions prepared by study sponsor or Contract Research Organization (CRO) to identify the potential and interest of a site/investigator to run a study successfully.

Confidential Disclosure Agreement (CDA)

Also referred to as a non-disclosure agreement (NDA), the CDA is a legal agreement between a minimum of two parties which outlines information the parties wish to share with one another for certain evaluation purposes, but wish to restrict from wider use and dissemination. The parties agree not to disclose the non-public information covered by the agreement. Sponsors most often times require a signed CDA before they will send information pertaining to a study.

Per official UF policy, UF PIs cannot be a party to such an agreement. Grants, contracts, and other agreements from external sponsors requiring signatures must be reviewed and signed by the Senior Assistant Dean, Office of Research Affairs.

Upon receipt of the CDA draft from the sponsor, the department enters the CDA into UFIRST for ORA review, negotiation and execution. Upon full execution of the CDA, the sponsor will send the department the following: clinical trial agreement (CTA), budget, regulatory packet (such as the protocol, investigator brochure, source documents, IRB documents, financial disclosure).

Clinical Trial Agreement (CTA)

The CTA is a legally binding agreement that manages the relationship between the sponsor providing the study drug or device, the financial support and /or proprietary information; and the institution providing data and/or results, publication, and input into further intellectual property. Upon receipt of CTA in MS Word format, the department reviews in concert with the CTA checklist.

The department will upload the CTA and the CTA checklist to UFIRST for ORA review, negotiation and execution. The CTA will be uploaded to UFIRST as a New Agreement.

For **Checklist for Clinical Study Agreements and other contract related forms** go to: ***F:\common\Research Studies\Office of Research Affairs (ORA)\Contract & Award Forms.***

Protocol and Regulatory Documents

The protocol, CTA (includes budget) and regulatory documents are managed simultaneously. The ORA manages the review, edits and negotiations pertaining to the terms and conditions within the CTA. The department manages the review, edits and negotiations for the budget and all regulatory materials. Communication with the sponsor is vital for successful completion of CTA and budget. For instruction on how to set up a regulatory binder, please see *Appendix C*.

Protocol Review
Protocol review is a critical component for successful budget negotiation. Read the protocol including footnotes in *Schedule of Assessments*. Hidden costs are most often found in study design, safety events, recruitment, and monitoring time.

Budget
Study preparation and start-up costs are **necessary**. The same activities and work is required to start up a study regardless of whether the clinical research site ends up enrolling one subject or ten subjects. Having a standard, non-refundable, non-negotiable fee schedule for start-up costs is crucial. *ORA has created a start –up fee budget template designed to be modified to meet the specifics of each study.* Please go to ***F:\common\Research Studies\Office of Research Affairs (ORA)\Budget Developmen***t.

Departments are highly encouraged to contact ORA via the ORA Request Portal (https://ufl.qualtrics.com/jfe/form/SV_3dvfjMe4Wd0qMgl) **for assistance with budget development and budget negotiation**. The budget for an industry sponsored clinical trial provides a breakdown of all fees associated with the study, outside of standard of care. In addition to per patient costs, the department must budget for UF's indirect costs, PI administrative time charge (3%), non-refundable start-up fees, pharmacy fees, screen failures, advertising and storage fees , as appropriate.
For a link to the F&A agreement, please visit:
https://research.ufl.edu/wp-content/uploads/FA-Agreement.pdf

Research Study Initiation Request Form
In order to determine costs for various clinical trial budget line items, the PI or their research administrator must prepare the Research Study Initiation Request Form (RSIRF). The final request must be completed and approved prior to enrolling patients. The form is then submitted to Grants Accounting. The final submitted copy is sent to Clinical Data Quality (CDQ) for EPIC build. Please see *Appendix D* for additional detail. Please note that use of the RSIRF form is required regardless of sponsor (industry, federal government, foundation, state).
For a copy of the RSIF form, please go to: F:\common\Research Studies\RSIF V2015.001
For research fee schedules, please go to:
Research technical fee schedule *F:\common\Research Studies\RSH TECH FEES*
Research professional fee schedule *F:\common\Research Studies\UF PHYSICIAN PROFESSIONAL SERVICES JUL2019.*

When the budget negotiation is complete, the PI or their research administrator should submit the finalized budget draft to ORA as part of the CTA.

Medicare Qualifying Studies
Medicare determines whether a clinical research study qualifies to bill patients/insurance for protocol-required routine costs. The Medicare Qualifying Studies Form (CMS billing verification form) is a required tool used to determine the costs. **The must be completed and signed by ORA and included in the submission of the initial RSIRF form.** The form and additional instructions are available at ***F:\common\Research Studies\Office of Research Affairs (ORA)\Forms.***

Pharmacy
The Department of Pharmacy is responsible for the control, storage, dispensing, and disposal of all medications used for research studies. In the case of inpatient studies, the Department of Pharmacy's Clinical Research Services needs to be involved as soon as possible to discuss budgeting and logistics.

Please see *Appendix E* for additional information and instruction.

Radiology
For clinical trials requiring CT, MR, NM, Angiography, PET procedures, or any other imaging modality, the department should submit radiological protocols to the Radiology Research Office through their website at: https://hscj.ufl.edu/radiology/research.aspx.

Pathology
Please see *Appendix F* – Guidelines for Engaging Pathology Collaborations for Research.

Nursing
Please follow instructions on RSIRF.

IRB Approval
UF requires Western Institutional Review Board IRB (WIRB) approval for all pharmaceutical industry sponsored clinical trials that are sponsor-initiated.

The PI or their research administrator should submit the WIRB application, clinical trial protocol, informed consent forms, and other documents requiring IRB approval and review to WIRB as soon as possible after the PI has chosen to participate in a pharmaceutical industry sponsored clinical trial.

Informed Consent
The institution requires all research submitted to and approved by WIB to utilize a special UF Informed Consent template located at: http://irb.ufl.edu/irb-04-home-western-irb/icftemplate.html

For industry-initiated clinical trials, informed consent forms (ICF) must be consistent with the CTA. A copy of the informed consent and a signed copy of the consent form checklist must be sent to ORA for review and approval. ORA staff members are available to assist the PI or their research administrator with the parts of an ICF that relate to the CTA. ***The Consent Form Checklist is located at F:\common\Research Studies\Office of Research Affairs (ORA)\Contract & Award Forms.***

Additionally, all WIRB studies must be reviewed for financial language assessment. Please refer back to page 3, **IRB Ancillary Review** for FLA Assessment process.

UFIRST Submission
When all documentation is completed and uploaded to UFIRST, click SUBMIT FOR REVIEW.

For **UFIRST Industry Sponsored process**, please go to ***F:\common\Research Studies\Office of Research Affairs (ORA)\Contract & Award Forms***. **Please note all industry sponsored clinical trials are Fund 214.**

Investigator-Initiated Funded Projects
The pre-award procedures for investigator initiated grant funded clinical trials, such as those funded by government agencies or private foundations, are essentially the same as those for industry initiated clinical trials above, except for a few notable differences.

Generally, a CDA is not required for non-pharmaceutical industry sponsored clinical trials.

The UF Institutional Review Board (IRB-01) rather than the Western Institutional Review Board IRB (WIRB) reviews and approves all non- pharmaceutical sponsored clinical trials.

Budgets for investigator-initiated grant funded opportunities must charge UF's negotiated federal DHHS F&A rate. For a link to the F&A agreement, please visit: https://research.ufl.edu/wp-content/uploads/FA-Agreement.pdf

Research Proposal Development
The first step in conducting an investigator-initiated grant funded research project is to develop a fundable research proposal. The Office of Research Affairs supports research proposal development from conception through grant submission. Utilize the ORA Request Portal to get started or to finalize a research proposal.

Funding Source
Once the research proposal is developed, the first step is to identify a funding source. To receive the weekly updates on funding opportunities, please contact "UF Funding Opportunities" FYI-L@LISTS.UFL.EDU or contact ORA via the portal request (https://ufl.qualtrics.com/jfe/form/SV_3dvfjMe4Wd0qMgl).
The pre-award procedures for investigator-initiated grant funded clinical trials generally require the submission of a research grant proposal rather than the execution of a contractual agreement. However, the research grant proposal guidelines, as well as the associated application and budget forms, are usually unique to each funding agency or institution.

Hence, unless the PI or their research administrator is very experienced with the preparation of research grant proposals for the particular funding agency or institution for which they are preparing it, they should first seek assistance and training from ORA staff members as soon as possible prior to the research grant proposal deadline. For a link to Proposal Preparation and Submission, please visit: https://research.ufl.edu/dsp/proposals.html

IRB Approval
UF requires UF Jacksonville Institutional Review Board (IRB-01) review and approval for all research grant projects that are not sponsor-initiated pharmaceutical industry sponsored clinical trials. The PI or their research administrator should submit all documentation required by IRB-01 for its review and approval sufficiently in advance to obtain approval before the projected begin date for the research project and in accordance with any sponsoring agency or institution guidelines.

UFIRST Submission
All research grant proposals must be entered into UFIRST. This includes the budget as well. The RSIRF form is required. UF requires approval for proposals prior to submission. UFIRST will electronically route the proposal and collect the required approvals. Budgets must follow the specific guidelines in the announcement. The Announcement will provide information concerning budget limitations, specific cost considerations, requirements for cost sharing, and other special financial information. Failure to adhere to budget or program guidelines may jeopardize funding for the proposal. UFIRST has access to all UF employee salary and benefits, allowing for the preparation of the budget within the system. Further, it applies the correct IDC and fringe pool rates to the budget.

UFIRST PROPOSAL DEADLINE AND POLICY
All proposals must be submitted to DSP TWO days prior to deadline. Any proposal submitted after the internal deadline will not be submitted by the University to the sponsor. Please see policy and FAQ at

https://research.ufl.edu/dsp/proposals/proposal-deadline-policy.html

Investigator Initiated Unfunded Studies

An investigator-initiated unfunded study is a research project that does not have a funding source. Investigator-initiated studies require the same components and oversight as funded research. The purpose or goal of unfunded research is to advance scientific/medical knowledge or verify a scientific/medical concept/idea that leads to any combination of the following: further research in a specified field, pilot testing, funded research, funding opportunities, publication and/or conference presentation.

UF requires UF Institutional Review Board (IRB-01) review and approval for all research grant projects that are investigator –initiated unfunded clinical trials.

The PI or their research administrator should submit all documentation required by IRB-01 for its review and approval sufficiently in advance to obtain approval before the projected begin date for the research project and in accordance with institution guidelines or any sponsoring agency guidelines.

For protocol development and any questions regarding IRB determination, please utilize the ORA Request Portal: https://ufl.qualtrics.com/jfe/form/SV_3dvfjMe4Wd0qMgl

Post Award

When the Department is notified that they have been awarded funding, they will receive the contract (CTA) and/or terms (Agreement) of the award from the funding agency. At that point, the department is required to:

- Create an agreement in UFIRST by linking the proposal to the agreement
- Upload the contract and terms provided by the funder
- Allocate the budget
- Submit for review

Notice of Award

- When all documentation is completed, uploaded and submitted to UFIRST the award will be routed to DSP. DSP staff will take ownership and review all data in the SmartForms, inclusive of budget information and compliance form responses. This is to ensure the budget release request is allowable per the terms and conditions of the funding document and to verify that the Award Compliance Form does not contain any obvious errors.
- DSP will input the terms and conditions for your Award. These terms and conditions will be present on the *UFIRST Notice of Award*. Once DSP has completed all levels of review and there are no pending issues to address, the DSP Owner will execute the *Complete DSP Review* activity to transition the Award to Contracts & Grants Review.
- C&G Owners will review the financial and management data. If changes are required they will send the Award back to DSP.
- When the Award is ready for release C&G will execute the *Initiate MyUFL Integration* activity. Here C&G will assign the chartfield and billing type.
- Upon completion the Award will transition to *Pending MyUFL Integration* state. This is an information state to indicate that the Award is in process of being released into myUFL for spending. The Award is active in MyUFL and funds may be utilized.

Award Management

Contracts and Grants (C&G) is responsible for establishing and maintaining contract and grant projects in the myUFL financial system and oversee the management of awards for compliance with sponsor's financial guidelines. C&G reviews expenditures to ensure costs are allowable, allocable, reasonable and consistent with funding agency regulations and advise PI's and administrators on university, state and federal guidelines. Additionally, C&G prepares and submits financial reports to sponsors; deposit and maintain records of payments received, assist auditors with data requests and reports and oversee close-out activity.

Deposit Log

The deposit logs contain information related to payments received and processed/deposited by Contracts and Grants Accounting Services. The processing time may vary depending on award setup; however, standard processing is typically a three business day turnaround.

Please note that a payment is considered to be "in process" until the deposit log notes a "deposit ID", which confirms that the payment has been posted. Please note that this log refers specifically to payments

received and deposited by our office, if you have specific questions relating to your award/project, please contact our office to speak with your grant administrator.
Link to deposit log: https://research.ufl.edu/cg/deposit-log.xlsx

Checks should be made payable to:
University of Florida Board of Trustees
Division of Sponsored Programs
207 Grinter Hall
P.O. Box 115500
Gainesville, FL 32611-5500
Phone: (352) 392-9267
Email: ufawards@ufl.edu

Once you receive the NOA that C&G has setup the research project account, you can invoice the sponsor for start-up fees and services, pay research participants and vendors, create requisitions for purchase orders, etc. within myUFL payment solutions (CORCENTRIC). Before you start the process, though, you will need to find information regarding the Chartfields, Available Balance, and Budget Ending date.

How to pay vendor (invoices)
Training and instruction: https://learn-and-grow.hr.ufl.edu/toolkits-resource-center/financial-toolkits/myuf-marketplace/

Invoicing is CTA specific. Please access the following links for instruction on how to manage funds and pay invoices in myUFL.

Chartfields
Training and instruction: (https://learn-and-grow.hr.ufl.edu/toolkits-resource-center/financial-toolkits/chartfields/)

A field that stores accounting information. Each grant project has 5 unique chartfields that include:

Project #: used to identify a specific account for a contract, grant, or capital project.

Department ID ("DeptID"): 8 digit department code (e.g., College of Medicine, Jacksonville is 30000000). It represents the unit that is accountable.

Fund Code is three digits long and represents where the money will come from (i.e., state, federal, industry, other restricted). The two codes you will see the most often with grant projects will be 201 (Federal); 214 (Industry) and 209 (other-restricted). Other codes you may see frequently are 211 (IDC/Overhead Accounts) and 212 (Residual Accounts).

Program Code is four digits and answers the question, "Why are you doing this action?" The most common and frequently used code is 2200 (Individual or Project Research).

Source of Funds is the code that describes where the funds originated. Industry is G000770, NIH is G000010, Residual is G000910, IDC/Overhead is G000800, etc.

The term Account is used to describe, "What you are doing." It is a classification of activities and is 6 digits long. For a list of Active Account Codes, please see *Appendix G.*

invoices in myUFL:

How to find a PI's awards/projects, detailed budget information and breakdown of costs
Main menu> myinvestigator
Enter one of the following fields: Project PI ID/Name, Dept. ID

How to add supplier
For a supplier to register or change their existing information with the University of Florida, send an email to the supplier directing them to the website below:
http://www.fa.ufl.edu/directives/supplier-portal/

How to transfer

myUFL toolkits
The following trainings are designed to help manage funded awards and utilize the toolkits as needed for refreshers/examples:

Sponsored Programs
https://learn-and-grow.hr.ufl.edu/toolkits-resource-center/sponsored-programs/

Financial
https://learn-and-grow.hr.ufl.edu/toolkits-resource-center/financial-toolkits/chartfields/

Travel and expense
https://learn-and-grow.hr.ufl.edu/toolkits-resource-center/financial-toolkits/travel-and-expense/

Enterprise Reporting
https://learn-and-grow.hr.ufl.edu/toolkits-resource-center/enterprise-reporting-toolkits/

UFIRST Award Modifications

Any changes, requiring sponsor approval or allowable internally must be routed through UFIRST via a modification for DSP to review. DSP will assist with identifying whether sponsor approval is required or not and whether or not additional information is required to process the modification.

Examples include:
Financial
Award dates
Compliance

For instructions:
https://research.ufl.edu/dsp/award-management/award-amendments.html

If you have any questions, please contact ORA.

Transferring UF Foundation funds in support of Sponsored Programs

UFF funds that will pay for activities that are subject to donor terms and conditions and require management, fiscal reporting or other compliance monitoring are to be transferred to a project in Fund

209, as authorized by DSP through the Notice of Award (NOA) Process, and then managed by C&G Accounting.
For instructions:
https://research.ufl.edu/dsp/award-management/fiscal-management/transferring-dso-uff-funds-to-uf-in-support-of-research-activities.html

If you have questions, please contact ORA.

Study Closeout

General Transaction Completion Procedures

To complete all transactions:

- Ensure that all revenue has been received from the sponsor and deposited into the research project account
- Ensure that all research project invoices have been paid and encumbrances closed

Industry initiated clinical trials

Closure of IRB will generate an audit of your study or upon IRB closure, you may contact audit services.

Audit services will schedule a time to meet with the administrative contact to review all financial documents. The purpose of the audit is to ensure all billing for research patients is in compliance with CMS and to ensure that all invoices have been paid in accordance with the CTA.

A detailed audit report will be sent to the PI and administrative contact with findings.

Upon completion of successful audit, a Request for Closure of Fund 214 will be sent to the administrative contact. C&G will then send a closeout memo to PI and administrative contact through UFIRST system. .
For form access, please go to: F:\common\Research Studies\Office of Research Affairs (ORA)\214 Closeout

For fixed price awards including clinical trials, the residual funds remaining at the end of the contract need not be returned to the sponsor. C&G Accounting has final approval to allow the direct component of the residual to be transferred to the PI's Miscellaneous Donors project. C&G Approval is obtained through the fixed price closeout process. The closeout memo will be sent via UFIRST.

Investigator-Initiated Grant Funded

The myUFL system will deliver early notification emails to the PI and the PI's Grant Administrator at 90, 45, and 0 days prior to the award's expiration date. The reminders ask the PI to review the project and take appropriate action (i.e. finish on time or request a no-cost extension).

Please visit Award Closeout for detailed information regarding Grant closeout at:
https://research.ufl.edu/dsp/award-closeout.html

Investigator-Initiated unfunded Studies

IRB closure generates the closure of the study. Please note that the IRB closure ceases all research activity.

Appendix A: IRB and HIPPA

What is Research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

What is a Human Subject?

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through *intervention* (*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject‟s environment that are performed for research purposes.) or i*nteraction* (*Interaction* includes communication or interpersonal contact between investigator and subject.) with the individual, or

(2) identifiable *private healthcare information* (*PHI)* which includes 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.)

(From 45 CFR 46 Sections 101 and 102) What is the IRB?

The IRB is a committee established by the University of Florida to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of UF. The IRB consists of MDs, PhDs, PharmDs, nurses, Chaplains, community and non-scientific members. It is the IRB‟s responsibility to review all research involving human subjects, approve, modify or disapprove studies upon consideration of human subject protection, certify that investigators are qualified to conduct research, place restrictions, suspend or terminate research proposals if needed, require progress reports from investigators and in some cases, observe the consent process of research involving human subjects.

What is HIPAA?

The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

The Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164.
The important thing to remember is that for research purposes, you are not permitted to spontaneously go through a patient‟s medical record without their express permission. If you wish to gather preliminary data in preparation for conducting a research study, you must apply for a certification to review records

preparatory to research. The same applies for research that involves collecting decedent information. There are instances
in which you can apply for a waiver of HIPAA authorization (just as you may apply for a waiver of consent in some cases) in order to conduct part or your entire research
project. This waiver, however, **must** be granted by the IRB prior to commencing viewing records or approaching patients.

For studies in which you will be using a consent form, your patients MUST sign a HIPAA-compliant document. At the University of Florida, all consents must conform to the University template, which automatically includes the required verbiage. The important thing to remember is that you must use the most current IRB applications and templates, which have HIPAA required questions and verbiage built in automatically.

There are stiff penalties, which include criminal, civil and invasion of privacy torts, for individuals who do not comply with the new HIPAA rules. HIPAA is a very serious and sensitive issue that the University takes very seriously. If you have *any* questions about whether or not something complies with the new HIPAA Privacy Rule, please contact the IRB office promptly. For more information about HIPAA and other privacy concerns, go to http://privacy.health.ufl.edu/.

What Happens if Research is Conducted without IRB Approval?

If research is conducted without IRB approval, you will place The University of Florida out of compliance with Federal requirements for human subjects research. This can result in Federal or IRB actions that will prevent you, your Department or The University of Florida from conducting human subjects research and will jeopardize The University of Florida human research certification from the Office for Human Research Protections.

Appendix B: Research Administration Basics for Clinical Trials

What is a clinical trial?

A clinical trial is a research study conducted with patients, usually to evaluate a new treatment or medicine, or to evaluate a new way to use an "old" treatment or medicine. Each trial is designed to answer specific scientific questions and to find better ways to treat individuals with a specific disease.

Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work.

Ideas for clinical trials usually come from researchers. Once researchers test new therapies or procedures in the laboratory and get promising results, they begin planning Phase I clinical trials. New therapies are tested on people only after laboratory and animal studies show promising results.

What is a research team?

The research team may include doctors and nurses as well as social workers and other healthcare professionals. A doctor (M.D. or PhD.) usually is the clinical trial Primary Investigator and takes ultimate responsibility for conducting the study.

Frequently a clinical trial will have a Research or Study Coordinator working on the team. The Research Coordinator may oversee, coordinate, and or implement the day to day activities of the clinical trial.

What is a protocol?

All clinical trials are based on a set of rules called a protocol. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

What are clinical trial phases?

Clinical trials of experimental drugs proceed through four phases:

In *Phase I* clinical trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In *Phase II* clinical trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
In *Phase III* studies, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase IV studies are done after the drug or treatment has been marketed. These studies continue testing the study drug or treatment to collect information about their effect in various populations and any side effects associated with long-term use.

What protections are there for people who participate in clinical trials?

The government has strict guidelines and safeguards to protect people who choose to participate in clinical trials. Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits.

An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected. All institutions that conduct or support biomedical research involving people must, by federal regulation, have an IRB that initially approves and periodically reviews the research.

What is informed consent?
Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. These facts include:

Why the research is being done
What the researchers want to accomplish
What will be done during the trial and for how long
What risks are involved in the trial
What benefits can be expected from the trial
What other treatments are available
Study participants have the right to leave the trial at any time

The research staff will give potential study participants informed consent documents that include the details about the study.

It is also a good idea for potential study participants to take the consent documents home and discuss them with family members or friends, or their physician.

Who can participate in a clinical trial?
All participants in clinical trials are volunteers. Some of the reasons that people volunteer to participate in clinical trials are:
To take an active role in their own health care; to gain access to new treatments that are not available to the public; to obtain expert medical care at leading healthcare facilities during the trial; and to help others by contributing to a broader scope of knowledge.

All clinical trials have criteria about who can get into the program. Criteria are based on such factors as age, type of disease, medical history, and current medical condition. Before joining a clinical trial, participants must qualify for the study. Some research studies seek volunteers with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Healthy volunteers participate in Phase I trials, vaccine studies, and trials on research on preventive care for children or adults.

The factors that allow participation in a clinical trial are called inclusion criteria and the factors that prevent participation are called exclusion criteria. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

Who sponsors clinical trials?
Clinical trials are sponsored by government agencies: such as the National Institutes of Health (NIH); pharmaceutical companies; individual physician – investigators; healthcare institutions such as health maintenance organizations (HMOs); and organizations that develop medical devices or equipment. Trials can take place in a variety of locations, such as hospitals, universities, doctors‟ offices, or community clinics.

What happens during a clinical trial?
The clinical trial process depends on the kind of trial. The research team may include doctors and nurses as well as social workers and other healthcare professionals. They will check a participant‟s health at the beginning of the trial, give specific instructions for participating in the trial, monitor participants carefully during the trial, and stay in touch with the participants after the study.

Some clinical trials involve more tests and doctor visits than normal for a specific illness or condition.

What is a placebo?
A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment‟s effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment.

What is a control or control group?
A control is the standard by which experimental observations are evaluated. In many clinical trials, one group or patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

What is a blinded or masked study?
A blinded or masked study is one in which participants do not know whether they are in the experimental or control group in a research study. Those in the experimental group get the medications or treatments being tested, while those in the control group get a standard treatment or no treatment.

What is a double-blind or double-masked study?
A double-blind or double-masked study is one in which neither the participants nor the study staff know which participants are receiving the experimental treatment and which ones are getting either a standard treatment or a placebo. These studies are performed so neither the patients‟ nor the doctors‟ expectations about the experimental drug can influence the outcome.

What are side effects and adverse reactions?
Side effects are any undesired actions or effects of drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.

What are the benefits and risks associated with clinical trials?
There are both benefits and risks associated with clinical trials. By participating in a clinical trial, participants can:

- Take an active role in their health care.
- Gain access to new treatments that are not available to the public.
- Obtain expert medical care at leading healthcare facilities during the trial. Help others by contributing to medical research.

Clinical trials have risks:

- There may be side effects or adverse reactions to medications or treatments. The treatment may not be effective.
- The protocol may require a lot of time for trips to the study site, treatments, hospital stays, or complex dosage requirements.

Should participants continue working with their primary healthcare provider if they participate in a trial?

Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but not extended or complete primary health care. In addition, by having the participant‟s healthcare provider work with the research team, it is possible to ensure that other medications or treatments will not conflict with the clinical trial protocol.

Will participants be paid for participating in a clinical trial?

Some clinical trials will pay for joining the trial, while others will not. In some programs, researchers will reimburse for expenses associated with participating the research. Such expenses may include transportation costs, childcare, meals, and accommodations.

Appendix C: Setting up a Regulatory Binder

General Guidance for Using the Regulatory Binder:
The Regulatory Binder should be established at the beginning of the study, prior to enrollment.

Keep the Regulatory Binder current and up-to-date.

Store binder in a safe and secure location, but accessible to study staff at all times. If sections of the binder are stored in a separate location (centrally filed) or maintained electronically, write a signed and dated note-to-file indicating the location and who maintains them. File the note behind the tab to which it applies.

Subject-specific documentation and information, e.g., signed consent forms, test results, and completed case report forms, should be maintained separately within the subject-specific binder/file.

Customize the binder to meet the needs of your protocol. Include only sections pertinent to your protocol. Sections can be added or removed as needed. If unsure of what sections to include/exclude, contact your local IRB or Human Subject Protection Program.

Applicable Sections:

All Studies:	Study Specific:
Protocol IRB Documents Consent Forms Staff CVs Staff Licensures Logs	Data Collection/CRF Lab Documents Drug/Device Accountability Sponsor DSMB Investigational Brochure

Applicable Sections:
The following is a detailed list to ensure that the applicable sections are maintained properly.

Protocol
Current protocol and all previously approved versions.
When applicable, a copy of the fully executed protocol signature page for original protocol and all approved versions. Outdated protocol versions can be kept either in a separate location or stored electronically. Write a signed and dated note-to-file indicating where previous versions are kept.

1. **IRB Documents**
   - Copies of all signed and dated IRB submissions and correspondences between the study site and IRB should be kept on file.
   - HSPP recommends filing documents in reverse chronological order to ensure that documentation provides an accurate history/timeline of study activity from approval to completion.

2. **Consent Forms**
    - Current IRB-approved consent form version(s) with the IRB approval stamp.
    - As soon as the IRB approves a new version of the consent form, the previous version expires. Previously approved versions can be kept in the IRB section of the Regulatory Binder.

3. **Staff CVs**
    - Signed and dated CVs for all study staff.
    - CVs should be updated every 2 years to verify that information is accurate and current.
    - CVs are filed collectively for the department; write a signed and dated note-to-file indicating the location.

4. **Staff Licensure**
    - Valid medical licenses/professional certifications for all IRB approved study staff.
    - Medical and nursing licenses should be renewed every 2 years in MA. It is important to monitor licensure expiration dates so that those nearing expiration can be promptly updated.
    - Include in this section, any professional certifications that verify staff eligibility to perform clinical procedures (e.g. phlebotomy, vital signs, ECG).
    - If medical licenses /certifications are filed collectively for the department, write a signed and dated note-to-file indicating the location.

5. **Logs**
    - Screening Log: Captures subjects who have been pre-screened to determine initial eligibility for enrollment.
    - Enrollment Log: Captures all subjects who sign a consent form.
    - Staff Signature Log/Delegation of Responsibility Log: Documents the study-related procedures delegated to staff. The PI should initial, sign and date this list, and update it as new staff or study procedures are added to the protocol.
    - Monitoring Log: Documents any form of study oversight/monitoring as defined in the IRB approved protocol.
    - Adverse Event Tracking Log: Tracks and ensures timely reporting of all applicable adverse events to the IRB.
    - Minor Deviation/Violation Tracking Log: Provides a record of all minor deviations from the IRB approved protocol.

6. **Data Collection/CRFs**
    - Blank set of CRFs, data collection sheets, and IRB-approved study questionnaires.

7. **Lab Documents**

- Current Lab Certification (e.g., CLIA, CAP).
- Normal Lab/Reference Values.

8. Drug Accountability

- Drug/Device shipment and receipt records
- Drug/Device Accountability Log.
- Most recent version of Investigator's Brochure or Device Manual.

9. Sponsor

- Copy of all significant correspondence to and from the study sponsor(s) (e.g., letters e-mails).
-

10. DSMB

- Copy of all Data and Safety Monitoring Board (DSMB) reports.
- Additional correspondences with DSMB (e.g. meeting minutes, information provided to the DSMB, emails).

Please note that the regulatory binder contents are one component of the quality improvement process and are used to ensure compliance with federal regulations, Good Clinical Practice guidelines, and Rutgers Policies. They should be used as a starting point to ensure compliance.

Appendix D: RSIF and EPIC Build

RSH Record Build and Maintenance:

Research Study Initiation Request Form (RSIRF)

- PI shows interest in participating in a study.
- Forwards request to Admin. Completes confidentiality forms, site selection visits, and questionnaires, etc.
- Receive approval from sponsor via startup package.
- Coordinator/PI completes sponsor forms, budget/contract and UFJP documentation requirements:
    - Coordinator/PI completes CMS Billing Verification Form and submits it to Office of Research Affairs for review and approval. Office of Research Affairs verifies NCT number via Clinical Trials website and IRB Number via Connexus.
    - Coordinator/PI completes Initial RSIRF documentation (mimics schedule of events/protocol) and submits it to Audit Services for review and signature.
    - Coordinator/PI submit other required forms (i.e. IRB initial protocol submission, Radiology and Pharmacy initiation form, nursing review form, etc.).
- Coordinator/PI Submits Final RSIRF to Audit Services for review.
- Audit services reviews for complete CMS Billing Verification Form, NCT Number and IRB Number. Sends approved RSIRF to CDQ-Reimbursement.
- CDQ-Reimbursement reviews for accuracy PB Codes and Charges then builds the RSH record in Epic. Sends notification to HB Reporting and Billing Analyst and Coordinator/PI that the RSH record has been built.
- HB Reporting and Billing Analyst completes the HB billing section of the RSH record and activates the study.
- Coordinator/PI associates patients to the study, which allows users to link orders and encounters as appropriate for research billing.
- Upon completion of a study, Coordinator/PI Submits Closed RSIRF to Audit Services.
    - Audit Services will forward closed requests to CDQ-Reimbursement for processing.
    - CDQ-Reimbursement reviews PB accounts and ensures all charges are processed and there are no balances left on the account.
    - Once all HB and PB balances are clear, CDQ-Reimbursement changes the billing status to Completed.

Billing:

PB Billing:

- Visit/Encounter is associated to the study at registration (see tip sheets for JP Clinics and JX Clinics).
- Provider/Coordinator generates charges during encounter. Orders can also be linked to the study (see tip sheet). System routes charges to appropriate PB/HB files.
- Charges linked to a study will generate a monthly billing statement.
- Charges for patients associated to a study but not linked/associated to the study, are routed to the Patients Needing Research Billing Review Report.
- Coordinator runs the Patients Needing Research Billing Review Report.
- Coordinator opens the Research Billing Review Activity to review the research patient charges, makes any needed 'bucket' corrections, and marks the services as reviewed. (See tip sheet).

- Charge enters Research Studies Charge Review Workqueue
- CDQ-Special Projects works charges in Workqueue and Completes Biller Review of Billing Review Activity:
    - Adds Q modifiers and diagnoses as needed
    - Follow up with BG to resolve BG edits/errors for resolution
    - Forwards study billing statements to Research Coordinator/PI
    - Follow up with departments for unpaid statement balances
    - Identify payment posting errors and report to cash for resolution
- CDQ-Special Projects enters missing charges, completes charge corrections and coordinate refund activities as requested by coordinators or audit services, both during the study and following study audits.
- Coordinators can send any billing questions to UFJaxResearchPysicianBilling@jax.ufl.edu

HB Billing:

- Provider generates charges during encounter. System routes charges to appropriate PB/HB files.
- HB Reporting and Billing Analyst runs a report to identify charges for patients that are Active on Treatment, but not marked as study related.
- HB Reporting and Billing Analyst sends spreadsheet of charges to Coordinator/PI to identify study-related versus bill-to-insurance charges.
- Coordinator/PI returns list to HB Reporting and Billing Analyst who finalizes billing.

Training:

- Coordinator/PI attends Epic training appropriate for their clinical or administrative role. Some roles may require both Physician based and Hospital Based training.
    - For UJFP Epic training, contact UFJPEpicTraining@jax.ufl
    - For JX or HB Epic training, contact JxEpic.physiciantrainer@jax.ufl.edu
- After obtaining Epic training and access, CDQ-Special Projects will conduct one-on-one training to cover study association, running study reports and how to work the Patients Needing Research Billing Review report for PB Charges.
    - Send request for training to UFJaxResearchPysicianBilling@jax.ufl.edu
- CDQ-Reimbursement and CDQ-Special Projects serve as a resource for a variety of Coordinator topics.

Resources:

Tina Bottini: Senior Assistant Dean, Research Administration and Compliance Office of Research Affairs University of Florida Health Science Center: Research Process and Policy, CMS Billing Verification
Anne Shumway: Research Administrator, Office of Research Affairs: Research Process and Policy
Phyllis Heba: Director of Audit Services: RSIRF Review/Approval
Andrew Wojcicki: Audit Manager: RSIRF Review/Approval
Kim Jones: CDQ-Special Projects Manager: Resolute PB Certified: PB Research Billing
Darin Morse: HB Reporting and Billing Analyst
Melissa Caperton: CDQ-Manager of Reimbursement and Quality Improvement: Research Billing Certified, Resolute PB Certified and EpicCare Ambulatory Certified: RSH Records and General Research Support
Erin Cox: CDQ-Special Projects: Resolute PB Certified: PB Billing Training to allow access to Epic Research Templates

Appendix E - Pharmacy Research Services

Pharmacy Services are provided by the UF Health Jacksonville, Department of Pharmacy, which may be contacted at:

Clinical Research Services (CRS)/ Research Pharmacist
SHANDS Jacksonville Medical Center (dba UF Health Jacksonville)
Department of Pharmacy
655 W. 8th Street
Jacksonville, FL 32209
Phone: (904) 244-3228 or (904) 244-6398
FAX: (904) 244-3499
researchpharmacist@jax.ufl.edu

Pharmacy Clinical Research Service (CRS)

All researchers on campus are encouraged to collaborate with the Department of Pharmacy for any clinical trials` involving investigational drugs. One of the objectives of the pharmacy's Clinical Research Service (CRS) is to ensure the safe use of investigational medications in our facilities.

Under Joint Commission regulations (Medication Management Standard 6.01.05), the Department of Pharmacy is responsible for the control, storage, dispensing, labeling and distribution/disposal of all medications within the organization, including those used for investigational studies. Therefore, all investigational medicines used in hospitalized patients or in hospital-owned clinics must be stored and dispensed through the hospital pharmacy or are subject to review, approval, supervision, and monitoring. For outpatient clinical trials, it is sometimes necessary for researchers to store and dispense investigational drugs outside the confines of the Pharmacy Department. In these areas, it is important to ensure that investigational drugs are maintained in a manner consistent with other drugs on campus and that procedures are consistent with Policy Rx-11-051, Investigational Drug Storage, Control and Dispensing in the Ambulatory Clinics.

All research coordinators are advised to review and be familiar with the policies and procedures of the organization particularly the policies listed below that address investigational agents:

- **Administrative Policies**
  - Administrative Policy (A-04-014) – Use of Investigational Drugs
  - Administrative Policy (A-01-055) – Protocol review/Requirements for IRB approval
- **Nursing Policies:**
  - N-01-117- Nursing IV Med Administration
  - Amb-04-012 Administration of Intravenous Medications
- **Medication and Pharmacy Procedures**
  - Rx-01-032 Pharmaceutical Waste
  - Rx-11-013 Medications Brought to the Hospital or Clinic by Patient
  - Rx-11-026 Medication Administration Protocol- Medical assistants
  - Rx-11-051 Investigational Drug Storage, Labeling & Dispensing in the Ambulatory Clinics

A. If there is any "medication" in the study, whether for standard of care or investigational, the "**Pharmacy Initiation Request Form**" form (**Part A**) must be completed and submitted to the pharmacy for review. *Medication* includes any investigational agent(s), FDA-approved medications, over-the-counter medications, herbals, nutritionals, etc.
   - **Pharmacy Initiation Request Form (Part A)**-listed on Infonet under forms/research/pharmacy initiation request form)

B. To ensure patient safety, any inpatient study involving a medication MUST be reviewed with the CRS prior to study initiation. *Inpatient* is defined as any patient admitted to UF Health Jacksonville, including 23-hour observation.

   CRS will be responsible for the following in these situations:
   1. Patient's pharmacy profile (to avoid drug duplication, allergies, overdose, etc.)
   2. Drug preparation and dispensing
   3. Appropriate drug storage and control
   4. Education of pharmacy personnel
   5. Investigational drug fact sheets (sent with the first dose of study medication; includes drug dosing and administration information, incompatibilities, side effects, etc.)

C. For UF Health Jacksonville outpatient clinic studies not utilizing the CRS, the Director, Department of Pharmacy, must approve all procedures for drug storage and dispensing ***if different*** from policy Rx-11-051 - Investigational Drug Storage, Control and Dispensing in the Ambulatory Clinics.

   1. Pharmacy personnel will conduct periodic inspections of these areas (for proper storage, labeling, etc.).

   2. The CRS is available to provide guidance to researchers for investigational medications stored and dispensed from University of Florida clinics affiliated with UF Health Jacksonville.

D. If utilizing the CRS for any study, see (**Part B**) for further instructions.

PHARMACY INITIATION REQUEST FORM
SHANDS JACKSONVILLE
UF HEALTH JACKSONVILLE

Date Submitted: _____

1. Will this research involve/require administration of any medication as a study objective or for standard of care?

   ☐ YES, go to Question 2
   ☐ NO, no need to complete or submit this form to pharmacy

2. Will you be utilizing the Pharmacy Clinical Research Service? (**MUST** utilize the Clinical Research Service for all inpatient studies)

   ☐ YES, please complete Items 3 thru 6 below and forward this form along with the following information to the Clinical Research Pharmacist (clinical center/basement) to initiate pharmacy budget review:

   - Research protocol
   - Investigator's brochure (if applicable)
   - Research Study Initiation Request Form (RSIRF)
   - IRB approval letter with Consent (this can be forwarded at a later date once approval is obtained)

   ☐ NO, Please complete items 3 thru 6 below and submit this form along with below to the Clinical Research Pharmacist (clinical center/basement).

   Note: Drug should be handled according to policy Rx-11-051 - Investigational Drug Storage, Control and Dispensing in the Ambulatory Clinics.

   - Clinic Name/Location of Medication Storage:_____
   - Research Protocol
   - Investigator's brochure (if applicable)
   - Research Study Initiation Request Form (RSIRF)

3. Will the study pay for any Adverse Events related to the protocol? ☐ YES ☐ NO

4. Protocol Information:

Protocol Title		
Sponsor of Project	Protocol No.	
IRB Number	WIRB Number	Anticipated Study Start Date
Expected Study Duration	Number of Patients Expected	Duration for Each Patient
Principal Investigator	Study Coordinator	Coordinator Phone Number

5. Where will study medications be administered and ordered and/or involved?

   ☐ Unit/Procedural area (if multiple, please list all):_____
   ☐ Clinic name (if applicable):_____

6. Drug List – please complete all fields.

	List of Drug(s) Used in Study	Drug Type	Standard of Care	Formulary	Payment *** who will pay for drugs	Drug use in conjunction with a procedure?	Payment of Procedure
1		□ Investigational □ IND exempt/FDA approved □ Non-approved indication/dose □ Non-FDA approved (e.g. herbal)	No Yes	No Yes	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____	No Yes_____ (if yes, list procedure)	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____
2		□ Investigational □ IND exempt/FDA approved □ Non-approved indication/dose □ Non-FDA approved (e.g. herbal)	No Yes	No Yes	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____	No Yes_____ (if yes, list procedure)	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____
3		□ Investigational □ IND exempt/FDA approved □ Non-approved indication/dose □ Non-FDA approved (e.g. herbal)	No Yes	No Yes	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____	No Yes_____ (if yes, list procedure)	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____
4		□ Investigational □ IND exempt/FDA approved □ Non-approved indication/dose □ Non-FDA approved (e.g. herbal)	No Yes	No Yes	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____	No Yes_____ (if yes, list procedure)	□ Sponsor □ Department Funds □ Patient/Insurance □ Other _____

*** Please specify, 'Other hospital-Sponsor' when the medication is being purchased by the Dept. of Pharmacy but will be billed to the sponsor.

EMAIL completed form and documents to researchpharmacist@jax.ufl.edu

Appendix F – Pathology

College of Medicine - *Jacksonville*
Department of Pathology

655 West 8th Street
Box C-505
Jacksonville, FL 32209
(904) 244-4387
(904) 244-4060 Fax

MEMO

TO: All

FROM: Shahla Masood, M.D., Professor and Chair, Department of Pathology Leon L Haley, Jr., M.D., Dean College of Medicine-Jacksonville Alex Parker, Ph.D., Senior Associate Dean for Research
Tina Bottini, Senior Assistant Dean, Research Administration

DATE: September 27, 2019

SUBJECT: Guidelines for Engaging Pathology Collaborations for Research

With advances in science and technology, there are an increasing number of requests to retrieve tissue samples from patients for research purposes. There is no doubt that collaborations with pathology as part of larger team science approach are a critical and an integral part of basic science, clinical and outcomes research at UF Health Jacksonville.

In order for the Department of Pathology to stay in compliance with "CAP Slide and Block Release", we must meet the regulatory requirements detailed in the CAP criteria list, ANP.12500. (see attached)

Criteria for Requesting Pathology Support

- Pathology collaborations must be requested during the protocol development, protocol review, or grant application process.
- Potential collaborators must share all protocols related to a particular study with the pathology department research coordinator to initiate the process for a feasibility study report. The sharing of these documents must be done to allow reasonable and sufficient time for pathology department review and discussion. The Department has set a minimum time requirement for review of 2 weeks (limit of one request each month per department).
- All studies will have appropriate IRB approval or registration as quality improvement projects.
- The collaborator will work with pathology department to ensure all pathology costs are included in the budget.
- Co-authorships will be made available to pathology faculty based on the level of contribution to the project.
- A collaborative model will be established for unfunded and pilot/preliminary studies.

Types of Requests

- Procuring and reviewing archival tissues with annotation as needed.
- Molecular and genetic studies, if available.
- Others – to be specifically requested and addressed.

Administration

- All Administrative activities will be performed promptly and within required timeliness.
- Pathology will assign a dedicated faculty based on the nature of the request.
- All negotiations including technical aspects will be done between the assigned pathology faculty and the specific Departmental research team.

Role of senior management including Deans, Chairs and CEOs

- Senior management will provide the vision and necessary support to the process described above and ensure the key role of research as part of the institutional mission.
- Any issues that cannot be resolved by the negotiating team will be forwarded to the Office of Research for review, resolution and remediation.

Appendix G – Active Account Codes

UFLOR	700000	OTHER EXP (4) - BUDGET ONLY	OTHER EXP
UFLOR	700001	E-RESOURCES (4) - BUDGET ONLY	E-RESOURCE
UFLOR	700002	TRAVEL/TRAINING(4)-BUDGET ONLY	TRAVEL/TRA
UFLOR	700005	OTHER EXP (5) - BUDGET ONLY	OTHER EXP
UFLOR	710000	CONTRACTUAL SERVICES	CONTRACTUA
UFLOR	711100	ACCOUNTING SERVICES	ACCOUNTING
UFLOR	711200	LEGAL SERVICES	LEGAL SERV
UFLOR	711300	CONSULTING SERVICES	CONSULTING
UFLOR	711500	ARCHITECTURAL SERVICES	ARCHITECTU
UFLOR	711600	ENGINEERING SERVICES	ENGINEERIN
UFLOR	711700	DATA PROCESSING SERVICES	DATAPRO
UFLOR	711800	ENTERTAINMENT SERVICES	ENTERSERV
UFLOR	711900	BANK CHARGES & CUSTODIAL FEES	BANK CHARG
UFLOR	712100	SUBCONTRACT <=25k (C&G Only)	SUBCONTRAC
UFLOR	712200	SUBCONTRACT >25k (C&G ONLY)	SUBCONTRAC
UFLOR	713000	ADVERTISING / MARKETING	ADVERTISIN
UFLOR	714000	CONSTRUCTION CONTRACTORS	CONSTRUCTI
UFLOR	715000	LECTURERS	LECTURE
UFLOR	715100	MEETING/TRAINING EXPENSE	MEETING/TR
UFLOR	715200	MEETING PLANNING SERVICES	MEETING PL
UFLOR	717000	LABORATORY SERVICES	LABORATORY
UFLOR	718000	HEALTH ASSESSMENTS	HEALTH ASS
UFLOR	719100	JANITORIAL SERVICES	JANITORIAL
UFLOR	719110	LAUNDRY SERVICES	LAUNDRY SE
UFLOR	719200	PARTICIPANT SUPPORT	PARTSPPT
UFLOR	719250	PARTICIP SUPP - NO FNA	PARTICIP S
UFLOR	719300	OTHER SERVICES - NON EMPLOYEES	OTHER SERV
UFLOR	719400	MOVING CONTRACTOR	MOVING CON
UFLOR	719500	HUMAN SUBJECT PAYMENTS	HUMAN SUBJ
UFLOR	719501	HSP EXPENSE - TM ONLY	HSP EXPENS
UFLOR	720000	UTILITIES & COMMUNICATIONS	UTILITIES
UFLOR	721100	ELECTRICITY	ELECTRICIT
UFLOR	721200	NATURAL GAS	NATURAL GA
UFLOR	721300	WATER	WATER
UFLOR	721350	SEWAGE	SEWAGE
UFLOR	721400	GARBAGE COLLECTION	GARBAGE CO
UFLOR	721500	STEAM	STEAM
UFLOR	721600	CHILLED WATER	Chilled Wt
UFLOR	721700	CABLE TELEVISION	CABLE TELE
UFLOR	721999	UTILITY REIMBURSEMENT	Util Reim
UFLOR	722100	TELEPHONE - LOCAL	TELEPHONE
UFLOR	722120	TELEPHONE INSTALL/MAINT/REPAIR	TELEPHONE
UFLOR	722130	TELEPHONE LEASING	TELEPHONE
UFLOR	722140	TELEPHONE CONTRACT	TELEPHONE
UFLOR	722150	TELEPHONE - LONG DISTANCE	TEL LNG DS
UFLOR	722200	CELLULAR PHONES & SERVICE PLAN	CELLULAR
UFLOR	722300	PAGERS	PAGERS
UFLOR	729100	UTIL & COMM - RESALE	UTIL & COM
UFLOR	729200	UTILITIES / COMM-OTHER	UT COMM
UFLOR	729900	FAX/PHONE EQUIPMENT <5000	FAX/PHONE
UFLOR	730000	MATERIALS AND SUPPLIES	MATERIALS
UFLOR	731100	LAB SUPPLIES	LAB SUPPLI
UFLOR	731110	GAS, LIQUID/COMPRESSED	GAS, LIQUI

UFLOR	731200	ANIMAL FOR RESEARCH <5000	ANIMAL FOR
UFLOR	731210	ANIMAL BEDDING AND SUPPLIES	ANIMAL BED
UFLOR	731220	ANIMAL FEED	ANIMAL FEE
UFLOR	731300	AUDIO/VISUAL SUPPLIES	AUDIO/VISU
UFLOR	731400	AGRICULTURAL SUPPLIES	AGRICULTUR
UFLOR	731700	MEDICAL EQUIPMENT <5000	MEDICAL EQ
UFLOR	731800	AUDIO/VISUAL EQUIPMENT <5000	AUDIO/VISU
UFLOR	731900	LAB EQUIPMENT <5000	LAB EQUIP
UFLOR	732100	OFFICE SUPPLIES - GENERAL	OFFICE SUP
UFLOR	732900	OFFICE EQUIPMENT <5000	OFFICE EQU
UFLOR	733000	BUILDING MAINT & SUPPLIES	BUILDING M
UFLOR	734100	COMPUTER SUPPLIES	COMPUTER S
UFLOR	734200	COMP SOFTWARE GENERAL	CMP SFTWR
UFLOR	734250	COMP SOFTWARE SPECIALIZED	CMP SFT TE
UFLOR	734260	ELECTRONIC DATA/SUBSCRIPTIONS	ELECTRONIC
UFLOR	734800	COMPUTER EQUIPMENT <5000	COMP EQUIP
UFLOR	734900	COMPUTER PERIPHERALS <5000	COMP-PERIP
UFLOR	735000	MEDICAL SUPPLIES	MEDICAL SU
UFLOR	735050	SURGICAL SUPPLIES	SURGICAL S
UFLOR	735100	BLOOD BANK/BLOOD PRODUCTS	BLOOD BANK
UFLOR	735200	SANITATION/STERILIZATION SUPL	SANITATION
UFLOR	736000	MOTOR FUELS AND LUBRICANTS	MOTOR FUEL
UFLOR	738000	MISC OTHER SUPPLIES	MISC OTHER
UFLOR	738100	UNIFORMS	UNIFORMS
UFLOR	738200	LINENS	LINENS
UFLOR	739100	MATERIAL AND SUPP - RESALE	MATERIAL A
UFLOR	739110	PHARMACY - RESALE	PHARMACY -
UFLOR	739300	BOOKS & PUBLICATN - NON LIB	BOOKS & PU
UFLOR	739400	EQUIPMENT > 1000 & < 5000	EQUIPMENT
UFLOR	739500	LIBRARY USE ONLY -RESOUCES<250	LIBRARY US
UFLOR	739700	SMALL HANDTOOLS <5000	SMALL-TOOL
UFLOR	739800	MUSICAL EQUIPMENT <5000	MUSICAL EQ
UFLOR	739900	FIREARMS <5000	FIREARMS
UFLOR	740000	REPAIRS AND MAINTENANCE	REPAIRS AN
UFLOR	741100	REPAIRS AND MAINT - BUILDINGS	REPAIRS AN
UFLOR	741200	MAINT CONTRACTS - BUILDINGS	MAINT CONT
UFLOR	741300	SAFETY MAINTENANCE / REPAIRS	SAFETY MAI
UFLOR	742100	REPAIRS & MAINT - FURN & EQUIP	REPAIRS &
UFLOR	742200	MAINTENANCE CONTRACTS - EQUIP	MAINTENANC
UFLOR	742300	REPAIRS & MAINT - VEHICLES	REPAIRS &
UFLOR	742400	RPR/MAINT-COMPUTER/ELECTRONICS	RPR/MAINT-
UFLOR	749000	REPAIRS & MAINTENANCE - OTHER	REPAIRS &
UFLOR	750000	SCHOLAR FELLOW LOANS & WAIV	SCHOLAR FE
UFLOR	751000	SCHOLARSHIPS	SCHOLARSHI
UFLOR	751110	RELEASE TO RECIPIENTS	RELEASE TO
UFLOR	751120	PAYBACKS	PAYBCKS
UFLOR	751200	Loan Advances	Loan Advan
UFLOR	751300	Loan Collections	Loan Colle
UFLOR	751601	NDEA PRIN CANC	NDEA PRIN
UFLOR	751602	PRIN CANC TEACHER	PRIN CANC
UFLOR	751603	PRIN CANC MILITARY	PRIN CANC
UFLOR	751604	PRIN CANC DEATH	PRIN CANC
UFLOR	751605	PRIN CANC DISABILITY	PRIN CANC
UFLOR	751606	PRIN CANC BANKRUPTCY	PRIN CANC

UFLOR	751607	PRIN CANC WRITE-OFF	PRIN CANC
UFLOR	751608	PRIN CANC SPEECH/PATH LANG	PRIN CANC
UFLOR	751609	PRIN CANC TE 10 PR 070172	PRIN CANC
UFLOR	751610	PRIN CANC TE 15 PR 070172	PRIN CANC
UFLOR	751611	PRIN CANC TE OTH ON/AFT 72	PRIN CANC
UFLOR	751612	PRIN CANC TE 20 PR 070172	PRIN CANC
UFLOR	751613	PRIN CANC TE 30 PR 070172	PRIN CANC
UFLOR	751614	PRIN CANC MIL PR 070172	PRIN CANC
UFLOR	751615	PRIN CANC MIL ON/AFT 070172	PRIN CANC
UFLOR	751616	PRIN CANC VOLUN ON/AFT 070187	PRIN CANC
UFLOR	751617	PRIN CANC HPSL 10	PRIN CANC
UFLOR	751618	PRIN CANC HPSL 15	PRIN CANC
UFLOR	751619	PRIN CANC UNCOLL PL100-607	PRIN CANC
UFLOR	751620	PRIN CANC NURSING	PRIN CANC
UFLOR	751621	PRIN CANC NURSING 10%	PRIN CANC
UFLOR	751622	PRIN CANC NURSING 15%	PRIN CANC
UFLOR	751623	PRIN CANC NURSING 20%	PRIN CANC
UFLOR	751624	PRIN CANC HPSL SHORTAGE	PRIN CANC
UFLOR	751625	PRIN CANC SUBJ ON/AFT 072392	PRIN CANC
UFLOR	751626	PRIN CANC LAW ON/AFT 112990	PRIN CANC
UFLOR	751627	PRIN CANC EARLY ON/AFT 072392	PRIN CANC
UFLOR	751628	PRIN CANC NUR/MT ON/AF 072392	PRIN CANC
UFLOR	751629	PRINC CANC DOE ASSIGN	PRINC CANC
UFLOR	751630	PRIN CANC PUBLIC DEFENDER	PRN CANC
UFLOR	751631	PRIN CANC LIBRARIAN SVC	PRIN CANC
UFLOR	751632	PRIN CANC PRE-K OR CHILDCARE	PRIN CANC
UFLOR	751633	PRINC CANC VA DISAB DETERM	PRINC CANC
UFLOR	751634	PRIN CANC FIRE FIGHTER SVC	PRIN CANC
UFLOR	752000	FELLOWSHIPS / STIPENDS	FELLOWSHIP
UFLOR	752100	HLTH INS FELLOWS W/ STIPENDS	HTH INS FE
UFLOR	753000	LOANS	LOANS
UFLOR	753100	DIRECT LOAN CANCELLATION	DR LN CN
UFLOR	753200	DIRECT LOAN ADJUSTMENT	DR LN ADJ
UFLOR	753300	DIRECT LOAN REFUND	DR LN REF
UFLOR	754000	WAIVERS	WAIVERS
UFLOR	759000	SCH/FEL/LOAN - OTHER	SCH/FEL/LO
UFLOR	759100	EMPLOYEE EDUCATION PROGRAM	EMPLOYEE E
UFLOR	759200	TUITION	TUITION
UFLOR	760000	LOAN CANC & ADJUSTMENTS	LOAN CANC
UFLOR	761101	COST CANC TEA 25 (ALL 349)	CST CN TE
UFLOR	761102	COST CANC TE 10/15 PR 070172	CST CN TE
UFLOR	761103	COST CANC OTH ON/AFT 070172	CST CN OT
UFLOR	761104	COST CANC HPSL	CST CN
UFLOR	761105	COST CANC NURSING	CST CN NU
UFLOR	761106	COST CANC DEATH	CST CN DTH
UFLOR	761107	COST CANC BANKRUPTCY	CST CN BNK
UFLOR	761108	COST CANC MILITARY	CST CN MIL
UFLOR	761109	COST CANC DISABILITY	CST CN DIS
UFLOR	761110	COST CANC WRITE-OFF	CST CN WOF
UFLOR	761111	COST CANC VOLUN ON/AF 070187	CST CN VOL
UFLOR	761113	COST CANC HPSL SHORTAGE	CSR CN HP
UFLOR	761114	COST CANC UNCOLL PL100-607	CST CN UNC
UFLOR	761115	COST CANC DOE	CST CN DOE
UFLOR	761116	COST CANC PUBLIC DEFENDER	COST CANC

UFLOR	769000	LOAN CANC & ADJ - OTHER	LOAN CANC
UFLOR	771005	DOMESTIC TRAVEL (5) - BUD ONLY	DOMESTIC T
UFLOR	771006	DOMESTIC TRAVEL (6) - BUD ONLY	DOMESTIC T
UFLOR	771100	IN STATE TRAVEL	IN STATE T
UFLOR	771200	OUT OF STATE TRAVEL	OUT OF STA
UFLOR	772000	FOREIGN TRAVEL	FOREIGN TR
UFLOR	772005	FOREIGN TRAVEL (5) - BUD ONLY	FOREIGN TR
UFLOR	772006	FOREIGN TRAVEL (6) - BUD ONLY	FOREIGN TR
UFLOR	773000	TRAVEL ADVANCES	TRAVEL ADV
UFLOR	773005	TRAVEL ADVANCES (5) - BUD ONLY	TRAVEL ADV
UFLOR	773006	TRAVEL ADVANCES (6) - BUD ONLY	TRAVEL ADV
UFLOR	774000	TRAVEL EXP DSO	TRAVEL EXP
UFLOR	780000	CAPITAL ASSET PURCHASES	CAPITAL AS
UFLOR	780006	CAP ASSET PURCH (6) - BUD ONLY	CAP ASSET
UFLOR	781000	LAND PURCHASE	LAND PURCH
UFLOR	781100	FURNITURE & EQUIPMENT >4999	EQUIPMENT
UFLOR	781150	COMPUTING EQUIPMENT-HPC ONLY	COMPUTING
UFLOR	782400	COMPUTER SOFTWARE >4,000,000	COMP SW
UFLOR	783200	MODULAR BUILDINGS	MODULAR BU
UFLOR	784000	VEHICL & TRANSP >4999	VEHICLES
UFLOR	785000	LIBRARY RESOURCES & PUBLICATNS	LIBRARY RE
UFLOR	786000	PROP UNDER CAPITAL LEASE-CAP	CAPLEASE
UFLOR	787000	CONSTRUCTION-WORK IN PROGRESS	CONSTRUCTI
UFLOR	788000	DEPRECIATION EXPENSE	DEPRECIATI
UFLOR	789100	ART & MUSEUM ARTIFACTS >4999	ART & MUSE
UFLOR	789400	LIVESTOCK >4999	LIVESTOCK
UFLOR	790000	OTHER OPERATING EXPENSES	OTHER OPER
UFLOR	791000	MEMBERSHIPS & DUES	MEMBERSHIP
UFLOR	791100	SUBSCRIPTIONS	SUBSCRIPTI
UFLOR	791200	PROFESSIONAL LICENSES	PROFESSION
UFLOR	792100	RENTALS - SPACE	RENTALS -
UFLOR	792200	RENTALS - EQUIPMENT	RENTEQUIP
UFLOR	792300	RENTALS - DORMITORY FURNITURE	RENTDORM
UFLOR	792900	RENTALS - OTHER	RENTALS -
UFLOR	793100	PHOTOCOPYING	PHOTOCOPYI
UFLOR	793200	OFFSET PRINTING	OFFSET PRI
UFLOR	793300	SPECIALTY PRINTING	SPECIALTY
UFLOR	793900	PRINTING REPRODUCTION - OTHER	PRINTING R
UFLOR	794000	POSTAGE	POSTAGE
UFLOR	794100	FREIGHT	FREIGHT
UFLOR	794200	COURIER SERVICE	COUR SERV
UFLOR	795000	INSURANCE	INSURANCE
UFLOR	795100	INSURANCE CLAIMS EXPENSE	INS CL EXP
UFLOR	796000	ROYALTIES PATENTS & COPYRIGHTS	ROYALTIES
UFLOR	797005	PATIENT CARE (5) BUD ONLY	PT CR LV 5
UFLOR	797006	PATIENT CARE (6) - BUD ONLY	PT CR LV 6
UFLOR	797100	PATIENT CARE COSTS	PT CR CST
UFLOR	799100	EXPENSE ADVANCES-C&G ONLY	EXPENSE AD
UFLOR	799200	AWARDS & COMMENDATIONS	AWARDS & C
UFLOR	799300	COLLECTION EXPENSES	COLLECTION
UFLOR	799400	FOOD & BEVERAGES HUMAN CONSUMP	FOOD & BEV
UFLOR	799500	UTILITIES TAX	UTIL TX
UFLOR	799600	ENTERTAINMENT EXPENSE	ENTERTAINM

UFLOR	799620	EVENT TICKETS	EVENT TICK
UFLOR	799700	LOBBYING (UFF FUNDS ONLY)	LOBBY
UFLOR	799800	RECRUITMENT EXPENSES	RECRUITMEN
UFLOR	799900	MISCELLANEOUS OPERATING EXP	MISCELLANE
UFLOR	800000	NON OPERATING EXPENSE	NON OPERAT
UFLOR	810000	TRANSFERS OUT - BUDGET ONLY	NON OP EXP
UFLOR	811000	TRANSFERS WITHIN BUSINESS UNIT	TRANSFERS
UFLOR	811005	TRANSFERS OUT CONSTRUCTION	TRANSFERS
UFLOR	812000	FACILITIES & ADMIN (C&G ONLY)	FACILITIES
UFLOR	812004	FAC & ADMIN (4) - BUDGET ONLY	FAC & ADMI
UFLOR	812005	FAC & ADMIN (5) - BUDGET ONLY	FAC & ADMI
UFLOR	812006	FAC & ADMIN (6) - BUDGET ONLY	FAC & ADMI
UFLOR	813000	ADMINISTRATIVE OVERHEAD	ADMINISTRA
UFLOR	813110	ADMIN OH-GENERAL ADMIN	ADMIN OH-G
UFLOR	813200	ADMIN OH-INFO TECH	ADMIN OH-I
UFLOR	813300	ADMIN OH-FACILITIES	ADMIN OH-F
UFLOR	813400	ADMIN OH-HSC ADMIN	ADMIN OH-H
UFLOR	813500	ADMIN OH-SPON PROJ ADMIN	ADMIN OH-S
UFLOR	813600	ADMIN OH- STUDENT SVCS	ADMIN OH-
UFLOR	813700	ADMIN OH-LIBRARY	ADMIN OH-L
UFLOR	813800	ADMIN OH-BOND PAYMENT	ADMIN OH-B
UFLOR	814000	TRANSFERS OF PROPERTY	TRANSFERS
UFLOR	817000	TRANSFER OUT FINANCIAL AID	TRANSFER O
UFLOR	818000	TRANSFERS WITHIN FUND	TRANSFERS
UFLOR	819000	FICA ALTERNATIVE-TRANSFERS OUT	FICAALTOUT
UFLOR	819001	SPECIAL PAY PLAN TRANSFER OUT	SPECIAL PA
UFLOR	820000	TRANSFERS TO STATE OF FLORIDA	TRANSFERS
UFLOR	820800	COMPONENT UNIT TRANSFER TO UF	CU-TRANSF
UFLOR	820900	TRANSFER TO UF COMPONENT UNITS	TRANSFERS
UFLOR	830000	INT ON CAP ASSET RELATED DEBT	INT ON CAP
UFLOR	831000	PRIN PMT-CAP ASSET RELATD DEBT	PRIN PMT
UFLOR	840000	FED CAPIT CONTRIBUTION REFUND	FED CAPIT
UFLOR	850000	INSTITUTIONAL CAP CONTR REFUND	INSTITUTIO
UFLOR	870000	BAD DEBT EXPENSE	BAD DEBT E
UFLOR	870100	STU FINANCIALS BAD DEBT EXP	STU FINANC
UFLOR	880000	INVESTMENT EXPENSE	INVEST EXP
UFLOR	890000	NON OPERATING EXPENSE - OTHER	NON OPERAT
UFLOR	891000	NET VENDOR DISCOUNTS	NET VENDOR
UFLOR	899999	NET CHECK SUSPENSE	NT CHK SUS