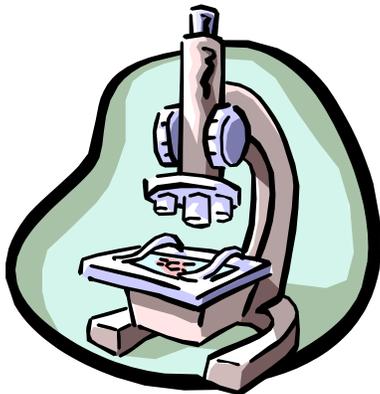


University of Florida COM - Jacksonville

Research Manual

Third Edition – May 2009



The How-To Book for
Research Administration
at UFCOM-J

What's Included:

- How to Prepare Budgets for Research Projects
- How to Setup your Research Accounts
- How to Register Research Patients
- How to Pay Bills
- Helpful Links, Forms & Contacts
- Guide on Research Policies & Procedures

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SECTION I: Introduction

The purpose of this research manual is to assist everyone involved with research administration at the University of Florida College of Medicine-Jacksonville (“UFCOM-J”) to understand the standard policies and procedures required for administering research studies at UFCOM-J. 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 a wealth of other information, such as UF PeopleSoft information system (“PeopleSoft”) instructions, fee schedules, and contact information.

Our affiliated teaching hospital, SHANDS Jacksonville, 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. The University of Florida Jacksonville Healthcare, Inc (UFJHI) is a health services support organization whose main function is the ownership and operation of the clinics that act as the feeder system for the campus. UFJHI and UFJPI are both “not for profit” corporations that support UFCOM-J. The combined efforts of all these organizations as UF&SHANDS afford exceptional institutional support for the research enterprise of UFCOM-J.

Office of Research Affairs

The Office for Research Affairs (ORA) is the UF Division of Sponsored Research (DSR) office for UFCOM-J. Information about DSR is available at <http://www.rgp.ufl.edu/research/>. DSR has also compiled a Researchers Handbook (available at http://www.rgp.ufl.edu/research/handbook/researcher_handbook/) that communicates official UF policies and procedures governing research for all of UF and is full of very useful information. Please note, however, that details of some UF policies and procedures are different for UFCOM-J and thus it is important to consult this UFCOM-J 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 UFCOM-J 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 (budgets and formats) to ensure compliance with University of Florida, Health Science Center, College of Medicine, 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 Director has official [signature authority](#) for research agreements and grant applications related to research conducted at UFCOM-J.

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.

In addition, ORA periodically organizes formal group training opportunities for various aspects of research administration. However, departmental research administrators, especially those who are new to UFCOM-J, may arrange for individual orientation and other in-service training with ORA staff at any time.

If you have ideas for improving this Research Manual or know of an item that needs to be revised, or if you need any other assistance with research administration, please call ORA at 244-9478 or visit the ORA office on the 9th Floor of Tower II, Suite 9015.

Institutional Review Board

Research projects to be conducted at UFCOM-J require approval from one of the following Institutional Review Boards.

IRB-03

For all research that is not a sponsor-initiated pharmaceutical industry sponsored clinical trial, the University of Florida Institutional Review Board (IRB-03) reviews and approves human subjects' research at the urban UF campus in Jacksonville and vicinity. It meets on the second and fourth Tuesdays of every month (except December). Anyone who would like to attend is welcome. Principal Investigators (PIs) are required to attend meetings when their research projects are being reviewed.

WIRB

For all research projects at the urban campus in Jacksonville and vicinity that are sponsor-initiated pharmaceutical industry sponsored clinical trials, UF has contracted with the Western Institutional Review Board (WIRB) to review and approve human subjects' research. Information regarding submissions for WIRB approval is available at <http://www.hscj.ufl.edu/irb> and <http://www.wirb.com>. A copy of all WIRB submissions must also be provided to IRB-03.

For more information about either IRB-03 or WIRB, please contact Sheila Heim at 244-9478 or stop by the IRB-03 office located on the 9th Floor of Tower II, Suite 9015, in the same office suite as ORA. You can also review the [IRB information](#) on page 38 of this Research Manual.

SECTION II: Pre-Award Procedures

Clinical Trials

For general background information about research administration for clinical trials, go to the [Research Administration Basics for Clinical Trials](#) section of this research manual on page 43.

Pharmaceutical Industry Sponsored

Pre-award procedures for pharmaceutical industry sponsored clinical trials generally involve the following components:

Confidential Disclosure Agreement (CDA)

- When a Principal Investigator (PI) requests the protocol and other specific information for a new clinical trial from a pharmaceutical industry sponsor, the sponsor usually wants the PI to sign a Confidential Disclosure Agreement or similar document (CDA) before they will send the information requested. Per official UF policy, UF PIs cannot be a party to such an agreement (see the [Signature Authority for Agreements](#) section of this Research Manual on page 36). In fact, by signing it, a PI may unnecessarily incur significant personal liability.
- Instead, the PI or their research administrator should always send the CDA to the Office of Research Affairs (ORA) located at Suite 9015 on the 9th Floor of Tower II (or email it to ORA@jax.ufl.edu). ORA staff will then review, edit, and negotiate it so that it will be acceptable for signature by the ORA Director who is the UF institutional official with designated [signature authority](#) to sign it.
- Once the CDA has been fully executed and returned to the sponsor by ORA, the PI should receive the regulatory packet with all the information needed from the sponsor (such as the protocol, investigator brochure, budget, contract, and IRB documents) to determine whether he or she wants to participate in the clinical trial.

Budget

- If the PI does choose to participate in the clinical trial, then the PI or their research administrator should negotiate the budget for the clinical trial with the pharmaceutical industry sponsor. ORA staff members are available to provide budget negotiation assistance and training.
- In addition to per patient costs such as those for clinical procedures, the PI or their research administrator should be sure to budget for UF's indirect costs (i.e., 25% IDC or overhead), UFJP's PI Administrative Time Charge (3%), non-refundable startup fees, Western Institutional Review Board (WIRB) fees, pharmacy fees, screen failures, advertising, and storage fees, as appropriate.

- In order to determine costs for various clinical trial budget line items, the PI or their research administrator should prepare the [Research Study Initiation Request Form](#) (RSIRF) (see page 80), mark it “Budget”, and then send it to SHANDS PFS & UF Audit Services as directed on the form.
- 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. Information about Pharmacy Services and their costs is available in the [Pharmacy Services](#) section of this Research Manual on page 55.
- For clinical trials requiring CT, MR, NM, Angiography, PET procedures, or any other imaging modality, the PI or their research administrator should submit radiological protocols to the Radiology Research Office. The Radiology Research Office will confirm what radiological procedures and services are necessary for the Department of Radiology to provide according to the radiological protocol as well as the costs for those procedures and services.
- When the budget negotiations with the pharmaceutical industry sponsor have been finalized, the PI or their research administrator should submit the finalized budget draft to ORA for incorporation into the Clinical Trial Agreement.
- The PI or their research administrator should then resubmit the RSIRF to SHANDS & UFJP marked “Final.”

Clinical Trial Agreement (CTA)

- Meanwhile, the PI or their research administrator should request a draft of the Clinical Trial Agreement or other similar contractual document (CTA) for the clinical trial from the pharmaceutical industry sponsor.
- If the pharmaceutical industry sponsor provides this draft CTA in a form that is not an electronic MS Word file, the PI or their research administrator should request that they send it in that form so that it can be revised using MS Word’s Track Changes function.
- The PI or their research administrator should provide the pharmaceutical industry sponsor with the following contact information for contract negotiations:
 University of Florida Health Science Center
 Office of Research Affairs
 9th Floor of Tower II, Suite 9015
 580 W. 8th St.
 Jacksonville, 32209
 (904) 244-9478
- In addition, the PI should complete and sign the Clinical Trial Agreement (CTA) checklist (available at http://rgp.ufl.edu/research/pdf/clinical_trial_checklist.pdf).

- As soon as both the CTA checklist and the electronic MS Word file of the draft CTA are available, they should be sent to ORA for CTA review, editing, negotiations, and routing for signatures. As with CDAs, UF PIs cannot sign as an official party to a CTA.
- Once ORA has finalized negotiations for the CTA with the pharmaceutical industry sponsor, it will route originals of the CTA to the PI for acknowledgement signatures (i.e., not as an official party to it), whenever applicable.
- The PI or their research administrator should then enter the clinical trial study information into the UF Start Proposal interface under the Grants\Proposals menu of PeopleSoft's MyUFL portal (for help with this [Start Proposal Procedure](#), see page 49). As a result, the PI or their research administrator will obtain the PeopleSoft proposal and project numbers to include on the DSR-1 form (available at <http://rgp.ufl.edu/research/pdf/dsr1.pdf>).
- Completion of the DSR-1 form will also require obtaining the pharmaceutical industry sponsor's account number for an overnight courier (such as FedEx).
- The PI or their research administrator should complete the DSR-1 form and the PI should sign it. The PI or their research administrator should then get the signature of the PI's chair (as well as that of the PI's Division Chief, if applicable) on the DSR-1 form.
- Once the PI has signed and returned the CTA originals along with the DSR-1 form to ORA, ORA will obtain signatures for the College Dean and Vice-President for Research on the DSR-1 form. ORA will then process the CTA originals for signature by the ORA Director who is the UF institutional official with designated [signature authority](#) to sign it.

IRB Approval

- UF requires Western Institutional Review Board IRB (WIRB) approval for all pharmaceutical industry sponsored clinical trials that are sponsor-initiated. However, non-pharmaceutical industry sponsored clinical trials that are investigator-initiated must be reviewed and approved by the UF Jacksonville Institutional Review Board (IRB-03).
- The PI or their research administrator should submit the WIRB (or IRB-03, as appropriate) application, clinical trial protocol, informed consent forms, and other documents requiring IRB approval and review to WIRB (or IRB-03, as appropriate) as soon as possible after the PI has chosen to participate in a pharmaceutical industry sponsored clinical trial.
- For pharmaceutical industry sponsored clinical trials, informed consent forms (ICF) must be consistent with the CTA. ORA staff members are available to assist the PI or their research administrator with the parts of an ICF that relate to the CTA.

Study Enrollment

Study enrollment for pharmaceutical industry sponsored clinical trials may begin upon receipt of the following:

- A fully-executed CTA
- IRB approval

ORA will then forward copies of the CTA, IRB approval certificate, DSR-1 form, and other related documentation to the main office of the UF Division of Sponsored Research (DSR) in Gainesville for processing and setup of the research project account.

Non-Pharmaceutical Industry Sponsored

The pre-award procedures for non-pharmaceutical industry sponsored clinical trials, such as those funded by government agencies or private foundations, are essentially the same as those for pharmaceutical industry sponsored clinical trials above, except for several notable differences.

- Generally, a CDA is not required for non-pharmaceutical industry sponsored clinical trials.
- The UF Jacksonville Institutional Review Board (IRB-03) rather than the Western Institutional Review Board (WIRB) reviews and approves all non-pharmaceutical industry sponsored clinical trials.
- Non-pharmaceutical industry sponsored clinical trials that 'flow down' from federal agencies as a sub-award through other institutions that are the primary awardees often require special attention to the federal regulations that govern UF as a sub-awardee which may be different than those that govern the primary awardee (depending upon the particular type of institution it is). ORA staff members are available to provide assistance and training with handling these differences in federal regulations.
- Budgets for non-pharmaceutical industry sponsored clinical trials that 'flow down' from federal agencies as a sub-award through other institutions generally must charge UF's negotiated federal DHHS F&A rate of 46.5% for indirect costs (aka IDC or overhead) rather than the 25% IDC rate for pharmaceutical industry sponsored clinical trials.

Research Grants

The pre-award procedures for research grants available from government agencies or private non-profit institutions such as foundations generally require the submission of a research grant proposal rather than execution of a contractual agreement. However, the research grant proposal guidelines, as well as 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.

In any case, sufficiently in advance of the research grant proposal deadline to allow time for review and revisions, the PI or their research administrator should submit the following documentation to ORA:

- A copy of the funding agency's or institution's grant proposal or application guidelines, program announcement, request for application (RFA), etc.
- A copy of the entire research grant proposal, including application and budget forms, appendices, & other associated documentation
- A copy of the abstract and a statement of work for the UF component if the research grant proposal is part of another institution's research grant proposal
- A Disclosure of Financial Conflict of Interest form (available at <http://rgp.ufl.edu/research/formstable.html>) completed and signed by the PI and all other key personnel (for federal agencies and any other funding agency or institution requiring it)

Federal Agency Grant Applications

Please contact ORA at 244-9478 for:

- guidance and assistance with the submission of federal agency grant applications via the Grants.gov web portal (<http://www.grants.gov>) as well as NIH specific proposals via the eRA Commons web portal (<http://era.nih.gov>)
- training and assistance with budget preparations

IRB Approval

- UF requires UF Jacksonville Institutional Review Board (IRB-03) 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-03 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.

SECTION III: Post-Award Procedures

After your research project has been approved by the appropriate IRB and you have either a fully executed contract or an award letter for it, as the case may be, ORA will forward the requisite documentation to DSR's main office in Gainesville to begin the post-award process.

Notification of Award/Acceptance (NOA)

The DSR Award Administration office issues a Notification of Award/Acceptance ("NOA") for all UF research grant awards or revenue received. The NOA is really just a summary of the grant award information, such as the project title, the PI, the department, the amount of funding, the sponsor name, etc. DSR will not issue an NOA if the required documents are missing, such as the IRB approval certificate, signed DSR-1 form (if required), fully executed agreement, agency award notice, etc.

A copy of the NOA issued for the first budget period and all back up documentation is also sent to ORA and the PI. In addition, ORA forwards this NOA to the PI's research administrator.

For pharmaceutical industry sponsored clinical trials, the **NOA will not be issued until UF receives the first payment**. Otherwise, the NOA is issued upon receipt of the notice of award from the sponsoring agency or institution.

Accordingly, if a research grant proposal is funded, the PI or their research administrator should send a copy of the sponsoring agency award letter to ORA right away. ORA will then activate the file for the research grant project and forward copies of all official documentation to the DSR Awards Administration office for issuance of the NOA.

NOTE: Your proposal must be entered into PeopleSoft using the [Start Proposal Procedure](#) before a Notification of Award/Acceptance will be issued.

Account Management

UF's Contracts & Grants Accounting Services (C&G) sets up and manages all research project accounts. C&G is responsible for interpreting and monitoring compliance with the financial administration requirements of various agencies, estimating and maintaining cash flow, collections and deposits, preparing billings, public vouchers, fiscal reports, and closeout documents, etc.

You can contact C&G at:

P. O. Box 113001
302 Tigert Hall
Gainesville, FL 32611-3001
Phone: (352) 392-1235 or 722-1235
FAX: (352) 846-0137

Once the DSR Award Administration office has issued the NOA, they will send it over to C&G for budget entry into PeopleSoft and to determine if any post-award forms are required. For example, if cost sharing was included in the proposal budget, C&G would

attach a Cost-Sharing Certification form to the NOA before sending it to the PI. (Note: C&G will not release the research project funds until they receive this completed Cost-Sharing Certification back from the PI).

You may query the C&G NOA processing log at <http://fa.ufl.edu/cg/>.

Account Setup

After receipt of the NOA, C&G will setup the account for the research project within the PeopleSoft system. The PI or their research administrator will receive a system generated e-mail notification of this account setup.

Deposits

All checks or other forms of payment should be sent or directed to C&G. C&G will attempt to match the payment with the appropriate research project account. If they are unable to match the payment to a research project account, they will place the funds into a holding account. If a payment is matched to a research project account, C&G will deposit the payment in that account and forward a copy of the check or other payment documentation to DSR Awards Administration for NOA processing.

If you suspect a payment should have been sent to C&G and you have not received an NOA for it, search for it in the C&G holding account and/or the Deposit Log online at <http://fa.ufl.edu/cg/>.

If you see a payment listed that you believe belongs to your department, contact DSR Awards Administration at 352-392-5991.

If a check or other form of payment is sent directly to the PI from the pharmaceutical sponsor, it should be sent along with a cover letter to C&G for processing. The cover letter should include the PI's name as well as the project and proposal numbers.

Overhead Accounts (also called Indirect Cost Accounts)

A portion of the overhead (or Indirect Cost) amounts received for each research project is usually available to transfer to an overhead account for the PI. If your PI does not yet have an overhead account, you will need to contact Carol Hunn at hunnc@ufl.edu in order to establish one. You need to give her the PI's name and UFID#.

Using PeopleSoft to Enter & Retrieve Account Information

Once you receive the NOA from DSR Awards Administration and C&G has setup the research project account, you can start processing requisitions for purchase orders, travel authorizations and reimbursements, paying research participants and vendors, etc., within UF's PeopleSoft information system (PeopleSoft). Before you start the process, though, you will need to find information regarding the Chartfields, Available Balance, and Budget Ending date.

You may access PeopleSoft via the MyUFL web portal at <https://my.ufl.edu/ps/signon.html>.

Chartfields

Many searches for information in PeopleSoft require provision of a set of chartfields.

Definition

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

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

Department ID (“DeptID”) is your 8 digit department code (e.g., Internal Medicine is 30050100). It represents the unit that is accountable.

Fund Code is three digits long and represents where the money will come from (i.e., state, auxiliary, or sponsored research). The two codes you will see the most often with grant projects will be 201 (Contracts & Grants, Federal Restricted) and 209 (Pharmaceutical Sponsored Clinical Trials, Other Restricted). Other codes you may see frequently are 211 (IDC/Overhead Accounts) and 212 (Misc. Residual Accounts).

Program Code is four digits and answers the question, “Why are you doing this action?” Some common program codes will be 2200 (Individual or Project Research), 1100 (General Academic Instruction), and 3100 (Patient Services).

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

Other frequently used terms:

The term Account is used to describe, “What you are doing.” It is a classification of activities and is 6 digits long.

Business Unit (for Purchasing transactions only) is the first four digits of your DeptID. For all other cases (besides Purchasing), the Business Unit will be UFLO or GRANT.

How to find your chartfields

You can find your chartfields once DSR has processed the first NOA for your grant project account and C&G has entered it into PeopleSoft. In PeopleSoft, go to:

Select Grants < Awards < Project Budget

Business Unit – enter GRANT

Project – enter your project number

Then select SEARCH

At the next screen, go to the “Detail Fund Distribution at Resource Level” section. Under that line will be four (4) tabs, which are “Resource Detail”, General Ledger Detail”, “Commitment Control Detail”, and “Grants Detail”.

Select the General Ledger Detail tab

You should now see your chartfields. The ones you will need for purchasing and payables include: Dept ID, Source, Fund, and Program (and, of course, your Project #).

You will not find your chartfields for your Misc Donor/Residual accounts or IDC/Overhead accounts using the above instructions. For those types of accounts, use the following chartfields:

Misc Donor/Residual Accounts:

Fund Code: 212
Source: G000910
Program code: 2200

IDC/Overhead Accounts:

Fund Code: 211
Source: G000800
Program code: 2200

How to find a PI’s grant awards (& project numbers)

In the PeopleSoft menu:

1. Click on Grants
2. Click on Awards
3. Click on Awards Profile
4. Enter the PI’s EMPID (which is his/her UFID) (the business unit should be “GRANT”)
5. Click Search
6. The grants for that PI should now be listed at the bottom of the screen
7. Click on any of them
8. Then look at the bottom right corner for the project number
9. For additional information, you can click on “Project” under the main menu (to the left)
10. Enter the Project # and make sure the Business Unit is “GRANT”
11. Click on Search

For those who are not a UF employee (e.g., those who are an employee of UFJHI), please fill out the [Travel and Expense Module Non-Employee Request form](http://fa.ufl.edu/forms/) (available at <http://fa.ufl.edu/forms/>) and fax it to the University Travel Office at 352-392-0081. Submission of this form will add you as a contact person on any entries you have in PeopleSoft. You will then receive e-mail notifications on the status of your payments and requisitions.

How to find your available budget

Before you process expenditures for a research project, you should always **check your available budget**.

Go to Commitment Control < Select Review Budget Activities < Budget Inquiry < Budgets Overview

Select the "Add a New Value" tab

Next to Inquiry Name, you need to name your search. I always use the project number. In any case, you can use an acronym, the project number, or whatever you would like.

Now click Search

Next Screen:

Under Budget Type, find "Ledger Group:". In the box, type in KKGMCHD. If your project is an IDC or Misc Residual Account, then type in CASH_BASED.

Go to the bottom of the screen and type in the Project # in both boxes next to Project ID (you can delete the % signs)

Now click on Save

(Please note: once you save this search, you may come back to view it without going through all of the above steps again. In other words, instead of selecting the "Add a New Value" tab, you will select the "Find an Existing Value" tab and type in whatever Inquiry Name you as assigned to that search.)

Click Search at the top of the screen

The next screen will show your Available Budget and Remaining Balance, including Direct and Indirect.

Go to Budget Overview Results (see screen shot on the next page) and click  for Direct; it will indicate Available Budget (see screen shot on the page after the next).



Search myUFL:

[Home](#) | [Worklist](#) | [Add to My Links](#) | [Suggestions](#) | [Alerts](#)

[My Links:](#)

Revenue Associated

[Display Options](#)

*Notes

Fetch

Ledger Totals (2 Rows)

Budget+Adjustment:	9,667.00	Available Budget:	5,319.86
Expense:	4,347.14	Net Transfer:	0.00
Pre-Encumbrance:	0.00	Associate Revenue:	0.00
Encumbrance	0.00	Remaining Balance:	5,319.86
Available Budget:	5,319.86		

Budget Overview Results

[Customize](#) | [Find](#) | [View All](#) | First 1-2 of 2 Last

Budget Chartfields [Budget Amounts](#)

	<u>Ledger Group</u>	<u>Department</u>	<u>Fund Code</u>	<u>Account</u>	<u>Project</u>	<u>Budget Period</u>
1	KKGMCCHD	30130100	209	DIRECT	00066482	CUM
2	KKGMCCHD	30130100	209	INDIR	00066482	CUM

[Return to Criteria](#)



Search myUFL:

[Home](#) | [Worklist](#) | [Add to My Links](#) | [Suggestions](#) | [Alerts](#)

[My Links:](#)

[New Window](#) | [Help](#) | [Customize Page](#)

Budget Details

Ledger Amounts

Budget:	7,733.60	USD
Expense:	3,477.71	USD
Encumbrance:	0.00	USD
Pre-Encumbrance:	0.00	USD

[Attributes](#)

[Parent / Children](#)

Associated Budgets

Associate Revenue: 0.00 USD

Available Budget

Without Tolerance:	4,255.89	USD	Percent:	(55.03%)	Forecasts
With Tolerance:	4,255.89	USD	Percent:	(55.03%)	

Budget Exceptions

Exception Errors: 0 Exception Warnings: 0

OK

How to find project start and end dates

Following the previous instructions for finding your available budget, now continue:

On the second screen entitled “Budget Details” (see screen shot on the previous page), look to the right of the screen for the word “Attributes” and click on it.

The next screen entitled “Budget Detail Attributes” will show the budget begin and end dates.

It is always a good idea to make sure your project has not expired. You will not be able to process purchase orders or invoices for a project that has an expired budget end date.

Please note that the budget end date coincides with the IRB expiration date, so it is important that you send a copy of the IRB approval letter with an updated expiration date (along with the PeopleSoft project and proposal numbers) to DSR Awards Administration (Fax# 352-392-4522) to request an extension for the project. DSR Awards Administration will then issue a new NOA for the extension.

If you received an invoice or need to make other expenditures after the project account is closed, which means the IRB approval period has expired, you can still extend the budget end date by sending an e-mail to an appropriate contact person at C&G. (For a list of C&G contacts sorted by Fund Source, see <http://fa.ufl.edu/apps/cg/sof/>; their corresponding e-mail addresses can be found at <http://fa.ufl.edu/directory.aspx?unit=cg>.) Please indicate the PeopleSoft project # and PI name when you send an e-mail to C&G for a budget end date extension along with a brief explanation. Usually, C&G can only extend the budget end date for few days so that you can process invoices and purchase orders.

Enterprise Reporting: Project Reports

PIs and their research administrators can find a collection of project reports to help meet their financial management needs via Enterprise Reporting. A help guide and report descriptions can be found online under Enterprise Reporting at <http://hr.ufl.edu/training/myUFL/Toolkits/reporting.asp>.

If you do not have “Enterprise Reporting” on your PeopleSoft MyUFL portal menu, please contact the Office of Research Affairs at 244-9478.

The Enterprise Reporting reports are listed by month and by one of three types:

- Summary Expense by Category for Grant Projects
- Expense Detail Report by Project
- Payroll Cost Distribution Summary for Grant Projects

Most pharmaceutical industry sponsored clinical trials will not have a Payroll Cost Distribution report, but the other two reports should be available for all research project accounts if you have received funds and have paid an invoice in the corresponding month.

To view these reports:

Go to Enterprise Reporting < Project Reports

Select 30000000 College-Medicine Jacksonville

Select your Department

Select PI

Select Project

If you have questions regarding the numbers in these reports, please contact the appropriate UF office: Purchasing 352-392-1331; Travel 352-392-1241; Payroll 352-392-1231; DSR 352-392-3516; or Contracts & Grants 352-392-1235.

If you have suggestions for improving these reports, please send an e-mail to helpdesk@ufl.edu and put "Grants Reporting" in the e-mail subject line.

Also, the following websites are available for additional resources, forms, and other useful information.

UF Purchasing: <http://www.purchasing.ufl.edu/>

Travel and Disbursement: <http://fa.ufl.edu/uds/>

UF Bridges: <http://www.bridges.ufl.edu/faqs/> (Frequently Asked Questions for different subject areas, such as Travel and Expense, Purchasing, Enterprise Reporting, etc.)

Expenditures

You can pay your bills and make other expenditures by means of vouchers, purchase requisitions, PCard, and travel reimbursement requests.

How to pay bills by voucher

A PeopleSoft **voucher** is an online request for payment that holds invoice information input by UF departments and fiscal offices and creates a payment schedule.

This process of paying through PeopleSoft will involve either an **encumbered voucher** or an **unencumbered voucher**. An encumbered voucher will mean you processed a purchase requisition through PeopleSoft and thus you encumbered

the funds. An unencumbered voucher is one where no purchase requisition was processed through PeopleSoft and thus the funds were not encumbered.

Encumbered

Instruction guides and Web simulations for paying encumbered vouchers When Receiving is Not Required (non Capital Equipment) and When Receiving is Required (Capital Equipment) are available at <http://www.hr.ufl.edu/training/myUFL/toolkits/vendors.asp>. This website also has instruction guides for how to use Voucher Inquiry, correct Voucher Errors, and do Voucher Imaging.

Unencumbered

The following is a list of allowed uses for unencumbered vouchers (per the Directives and Procedures) instead of creating a purchase order. Please see <http://www.hr.ufl.edu/training/myUFL/toolkits/vendors.asp> and follow the instructions for Paying Unencumbered Vouchers.

The following items are allowable for using an unencumbered voucher:

- Petty cash reimbursements
- Research participants*
- Clinical trial expenditures
- Utilities/Telephone
- Freight
- Postage
- Cellular charges
- Memberships/Subscriptions
- Employee reimbursements (needs a clear business purpose for the Justification on the voucher)
- Direct travel payments (car rental, conference registrations, entry fees, and hotel payments)
- Advertising
- Fellowships/Tuition/Scholarships (non-payroll)
- Settlement agreements
- Notary charges
- Awards (see section 4(B))
- Student and Housing refunds
- Self-Moves (when a department only allows a small amount towards moving expenses and the new faculty/staff member elects to move their own household goods)
- Proctoring Services
- Licenses
- Insurance
- Royalty payments
- Honorariums

- Employee/Student verification services (background check, credit check, SSN verification, etc.)
- Taxes (payroll, property, intangible, etc.)
- Agency fund expenditures (991 fund)

*For paying a Research Participant

Request that each individual Research Participant be added to the vendor file by sending a W-9 form for them by either e-mail (addvendor@udl.edu) or fax (352-392-0081).

In addition, a Participant Support form needs to be filled out by the department. Send it to Accounts Payable when you process a payment thru PeopleSoft (see page 24 on [How to pay an unencumbered voucher](#); the form acts as an invoice).

These forms can be found at <http://fa.ufl.edu/forms/>.

Once these forms have been submitted, you can use an unencumbered voucher to create the request for payment to the research participant.

Please follow the instruction guide and Web simulations at <http://www.hr.ufl.edu/training/myUFL/toolkits/vendors.asp> for help with paying an Unencumbered Voucher, Voucher Inquiry, Payment Inquiry, etc.

For UF employees being paid as a Research Participant

Please make payments to them using the Payroll module through “Additional Pay.” Do not add them as a vendor. For more information, please refer to the Additional Pay instruction guide at <http://hr.ufl.edu/training/myUFL/Toolkits/HiringAddPay.asp>.

How do I reimburse an employee, such as a faculty member, for non-travel expenses?

Use an unencumbered voucher to create the request for payment to the employee. If the employee is not in the vendor file, e-mail addvendor@ufl.edu to request that the individual be added to the vendor file. Include in your message a statement that the individual is a UF employee for whom you are requesting reimbursement, their UFID, and what specifically is being reimbursed.

When completing the voucher request, be sure to include a “Comment” (link on the Invoice Information tab) that contains a justification why normal purchasing procedures (requisition or PCard) were not used.

Then, follow the process on [How to Pay an Unencumbered Voucher](#) on page 24.

How will I know the vendor was actually added to the PeopleSoft vendor file?

You have two options:

1. Navigate in PeopleSoft to Vendor > Set Up Maintenance > Vendor Information. The best practice for searching for a vendor is to use the “contains” option with the Name 1 field and then put one word from the vendor name into the Name 1 field. If there are no results that match what you are looking for, search ShortName “contains” and put just the first eight (8) letters of the first word in the company name or individual’s last name.

After finding your vendor, please be sure to click VIEW ALL in the Address tab so that all available addresses will appear. For more information, there is an instruction guide on Finding Vendors at

<http://www.hr.ufl.edu/training/myUFL/toolkits/purchasing.asp>

2. Request that the vendor send you the information required by UF and then fax that information to Vendor Maintenance at 352-392-0081 with your email request on the coversheet or as an attachment. If all required information is received, you will then receive an email confirmation that the vendor has been added.

Imaging

After processing a voucher, instead of mailing invoices and supporting documentation to the appropriate office or to Purchasing and Disbursements at Elmore Hall, fax the paperwork directly to a fax server (352-846-1020) that automatically scans it into their system. This way, approvals of vouchers will be much faster (within minutes). You can use Voucher Imaging for both Encumbered and Unencumbered vouchers.

How to process a purchase requisition

External Vendors

The following instructions and web simulations are available at Financial Toolkits – Purchasing at <http://www.hr.ufl.edu/training/myUFL/toolkits/purchasing.asp>:

- Creating a Simple Requisition
- Creating a Requisition for an Asset
- Creating a Service Requisition for a Temp Clerical
- Creating a Service Requisition for Time and Material
- Creating a Requisition to a UF Vendor
- Using the Manage Requisitions Page
- Using the PO Information Page

- Receiving a Purchase Order - Assets
- Creating Multi-Line Requisitions
- Receiving items
- Receiving Assets
- How to Find a Purchase Order Number
- How to Print a Department Copy of a Purchase Order, etc.

Please note that equipment costing over \$1,000.00 (Capital Equipment) requires a purchase requisition. Accounts Payable will not process the unencumbered payment for equipment over \$1,000.00 without a purchase order.

Also, some equipment, such as copiers, computers, and scientific equipment, are under State and/or UF contract. Please see the list of these equipment items at http://www.purchasing.ufl.edu/main_contracts.asp.

UFJHI/UFJP Invoices

Purpose

The purpose of this procedure is to define how to prepare a requisition that later becomes a purchase order to pay UFJHI using grant funds for payment of UFJHI employees working on a grant funded project.

General

This procedure is used when a University of Florida investigator uses employees of University of Florida Jacksonville Healthcare, Inc. (UFJHI) in a grant funded study. UFJHI will need to invoice the UF investigator for the salaries. This UFJHI invoice is paid using a purchase order for the salaries (or portions thereof).

Procedure

Accordingly, you should work with UFJP to obtain an invoice for the research staff to be paid from the UF account. Once a purchase order has been assigned and the invoice has been received, the payment can be processed through PeopleSoft. Please see [How to Process a Purchase Requisition](#) on page 26 and [How to Pay an Encumbered Voucher](#) on page 24.

I have more questions. Who can I contact?

For further questions regarding how to use various features and functions of PeopleSoft pertaining to research projects, please contact the Office of Research Affairs at 244-9478.

For technical problems using the PeopleSoft myUFL web portal, please contact the UF Help Desk at helpdesk@ufl.edu or call 352-392-HELP.

How to pay by PCard

Overview

- What is a PCard?

The University of Florida Purchasing “PCard” is a VISA credit card issued by Bank of America.

- How Does a PCard Work?

Just like a regular credit card. It's fast and easy, no waiting for a purchase order number and vendors are paid more quickly.

- Who Can Get a PCard?

PCards are for UF staff, faculty, graduate assistants, and OPS (technical and professional) employees who make purchases or travel for official University business. PCards may not be issued to students who are not employees. PCards can only be issued to individual UF employees whose Dean, Director, or Department Chair authorizes the request.

- Who Pays for the PCard?

Your department pays PCard charges. Please be sure that your department has the appropriate budget available before making the charge.

Cardholders are personally responsible for inappropriate use of the PCard and are subject to disciplinary action for misuse.

- How are charges paid?

All PCard users must have Verifiers/Approvers who process their PCard transactions. Verifiers/Approvers are responsible for obtaining receipts from cardholders and electronically processing appropriate charges based on those receipts. Verifiers/Approvers are established within each department. If you are not sure if you have a Verifier/Approver, check with your department fiscal staff. Cardholders can reconcile their own charges but must have a separate approver.

- How do I get a PCard?

The steps to getting a PCard are:

- Take the on-line training and pass a quiz
- Complete the Cardholder Agreement
- Complete the PCard Application and have it approved by your Dean, Director, or Department Chair

- How long does it take to get a PCard?

Fully completed requests take up to ten working days for a card to arrive once it has been ordered. Cardholders will be notified via email once their PCard has arrived. PCards can be picked up from Elmore Hall between 8:30am and 12pm or 1:00pm and 4:30pm.

Quick reference to appropriate PCard use: see

http://www.purchasing.ufl.edu/PCD_WBT/pcdindex.asp.

To see how to reconcile PCard transactions, please see Reconciling PCard Transactions at <http://hr.ufl.edu/training/myUFL/Toolkits/purchasing.asp>.

For additional information regarding the PCard, please refer to

http://www.purchasing.ufl.edu/main_purchasingcards.asp.

How to pay travel expenses

Please see <http://fa.ufl.edu/uco/handbook/handbook.asp?doc=1.4.14> for guidelines on travel related expenditures if you are not familiar with them.

Before the Travel Occurs: Travel Authorization

Before the travel occurs, a Travel Authorization (TA) is **mandatory** for travel to conferences, conventions, or foreign locations, and to request a Cash Advance.

After the Travel Occurs: Expense Report

After the travel occurs, you will need to submit an Expense Report. While the Travel Authorization was an estimate of expenses, the Expense Report is an accounting of the actual expenses incurred for reimbursement to the Traveler.

Signed travel Expense Reports and all supporting documentation should be sent immediately after processing a travel Expense Report in PeopleSoft. Attach the receipts and backup to the signed travel Expense Report signature page and forward to:

University Travel Office

PO Box 115350
114 Elmore Hall
Gainesville, FL 32611-5350

For instructions on how to create a Travel Authorization or an Expense Report, or for other travel related processes in PeopleSoft, please see <http://www.hr.ufl.edu/training/myUFL/toolkits/TravelandExpense.asp>.

For further enquiry about travel expenses, contact the University Travel Office at 352-392-1245:

Institutional Fees

Some institutional fees are routinely deducted from the research project account, such as those for indirect costs (i.e., IDC or overhead) and the PI Administrative Time Charge.

Indirect Costs (i.e., IDC or Overhead)

UF's Indirect Cost Policies

UF's policy is that all revenue received for sponsored research projects is assessed overhead/indirect costs (which are 25% for industry sponsored trials and 46.5% for federal agency sponsored research projects; see <http://rgp.ufl.edu/research/idc.html>). Our Contracts & Grants office WILL NOT track individual exceptions to this policy for clinical trials (i.e., they will use only a Total Direct Cost basis without modifications, such as for costs that are not calculated per patient) and thus, whether or not it's provided for in the budget, it is assessed to all funds received for clinical trial projects in all cases.

The UF indirect cost policy is also clearly communicated to all PI research managers/coordinators in the following excerpts from their Clinical Trial Agreement Processing Guide:

The indirect cost rate is negotiated with the U.S. Department of Health and Human Services (UF's cognizant audit agency) and reflects the rate of reimbursement for real, audited, facilities and administration costs incurred in the conduct of research. Included among these costs are: depreciation and use allowance costs of buildings and equipment, maintenance and repairs, janitorial services and utilities, hazardous waste disposal; libraries; and general administrative costs such as sponsored programs administration, departmental and general administration (such as accounting, purchasing, legal services, and personnel compliance). These costs are "indirect," or general research support costs, because they are not included in the "direct" portion of the budget allocated for specific project research and typically cannot be ascribed to an individual project. They relate to the conduct of research in general, regardless of the source of funding, and therefore *must be applied to all grants and contracts*.

Effective July 1, 1995, all grants, contracts, and agreements accepted from any sponsor to fund University research must be charged the full on-campus and off-campus indirect cost rates established for federal awards (with the exception of clinical trials which have a standard indirect cost rate of 25% of total direct costs [TDC]).

UF's indirect cost policies apply to all clinical trial project revenue, regardless of whether it is per patient or not.

F&A (IDC) Rates

The current UF F&A (IDC) Rates are available at: <http://rgp.ufl.edu/research/idc.html>.

Budgeting Indirect Costs

Indirect costs (IDC) for non-federal clinical trials at the University of Florida have a set indirect cost rate of 25% of total direct costs (TDC). When budgeting, add 25% of the direct costs to your total. Example; \$1,000 of direct x 1.25% = \$1,250 total cost.

Indirect Cost Recovery

When payment is received indirect costs are assessed at the flat rate of 25% of actual cash received. For example a \$1,250 payment is received from a clinical trial sponsor. The funds are credited to your project as follows; $\$1,250/1.25 = \$1,000$ Direct Cost and \$250 of Indirect Costs. The direct component is the amount available to the PI to cover project costs.

Per UF policy, only costs that are invoiced by outside vendors can be treated as 'pass-thru' expenses that are exempt from the assessment of these indirect costs, as long as the industry sponsor pays the outside vendor directly.

PI Administrative Time Charge

By direction of the Dean, the Finance Committee was asked to recommend a method of budgeting and accounting for the administrative time of Principal Investigators and Support Staff in grants where administrative FTE's are not specifically funded. This situation applies more often to pharmaceutical studies. The Finance Committee's recommendation, which was approved by the board, was that such grants would be billed a flat 3% against all funds received. This amount would offset a portion of the salary and benefits expense of the PI. This amount would be billed and transferred from the appropriate fund in Gainesville each quarter. It was agreed by the Research Process Committee that this function would be handled by the Grants Manager (Audit Services).

Account 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.
- Transfer any residual funds to a Miscellaneous Donors Account.

C&G Procedures

If you have a research project that is complete (i.e., all revenues have been received and all bills have been paid, and the IRB approval period has been closed), you can contact Contracts & Grants to closeout the account. (See the list of appropriate C&G contact persons at <http://fa.ufl.edu/apps/cg/sof/>.)

Your next step would then be requesting a closeout letter from C&G. Have the PI confirm and sign this letter, and then send it to ORA. After signature from ORA's Director is obtained, ORA will forward the closeout letter to C&G.

Miscellaneous Donors Account (also known as Miscellaneous Residual Account)

A PI can put residual funds from fixed fee accounts (most pharmaceutical industry sponsored clinical trials are fixed fee) into these accounts, when allowable. You can refer to the contract or grant guidelines to see if this is allowable.

If the PI does not have a Miscellaneous Donors/Residual Account already, you will then need to complete a DSR-1 form (<http://rgp.ufl.edu/research/pdf/dsr1.pdf>) in order to open one. Have the PI and Chair sign both the DSR-1 form and the closeout letter. Then bring it to ORA for signature (please note that the Chair will only be required to sign the closeout letter if requested within the document). On the closeout letter, you should check the line that states "Transfer to Miscellaneous Donors Acct #:" and then write/type in "TBA". Both original documents will need to be sent to Office of Research Affairs, UF Health Science Center-Jacksonville, located at Tower II, Room 9015. The Office of Research Affairs will then forward the documents to Contracts and Grants in Gainesville.

If you are unsure whether the PI has one of these accounts already, please contact the Office of Research Affairs at 244-9478.

Ongoing Responsibilities

Schedule and Register your enrolled patients as described in the Appointment Scheduling Process for Research Study Patients Policy ([AMB-016-01](#)) (page 76) and Registration Visit Flow and Billing for Research Study Patients Policy ([AMB-016-02](#)) (page 77).

Registration, Admission, & Ordering

1. Contract billing should be utilized for all research related outpatient services.
2. To register a research outpatient, fax a registration form to the Clinical Laboratory to obtain a contract account number.
3. Write the contract account number on your test requisition*. Complete the patient demographic fields, check off the required tests, and send the test requisition along with the patient or specimen to the appropriate charge department for testing.
4. Contract Billing can also be utilized when an existing in-patient requires research related ancillary services. Complete steps 2 and 3 above to re-register the patient and to place your research orders. Note: the patient will have two active account numbers in the system. The research account is linked to patient type RES. Be sure to use the correct account number to avoid charge errors.
5. Contract Billing cannot be utilized for patients admitted solely for research purposes (as an in-patient or for observation or ambulatory surgery). Complete a [Research Patient Referral Form](#), attach a copy of the patient's insurance card (if the patient's insurance will be billed primary to the study), and send it along with the patient to the Admissions Department for processing.

*Test requisitions are located in the network folder F:/common/research studies/test requisitions

Research Project Closure

Besides closeout of the research project account, there are other procedures for closure of the research project with the IRB (or WIRB), the Pharmacy, and the project sponsor.

IRB

For IRB-03 project closure, see <http://www.hscj.ufl.edu/irb>.

For WIRB project closure, see
http://www.wirb.com/content/quick_notify_wirb.aspx.

Pharmacy

Study closure procedures for Pharmacy are described in the Pharmacy Services, [Study Closure](#) section on page 60.

Project Sponsor

Please contact the individual project sponsor for their project closure procedures.

SECTION IV: Appendices

Signature Authority for Agreements

Office of the Senior Vice President for Health Affairs

October 4, 2007

MEMORANDUM

TO: All Faculty, Administrators, and Staff

FROM: Douglas J. Barrett, M.D.
Senior Vice President, Health Affairs

SUBJECT: Signature Authority for University Health Science Center Agreements/Contracts

Did you know that you and your family may be at personal financial risk if you inappropriately sign an agreement/contract on behalf of the University?

Those who may sign have been so designated by an express, written, category-specific delegation of signature authority issued by the President of the University of Florida on behalf of the University of Florida Board of Trustees. The University President's written signature delegation has been extended to the Senior Vice President, Health Affairs, the deans of the Health Science Center colleges, and a limited number of other specified individuals, and only for certain types of agreements/contracts.

The exclusivity of official University signature authority for executing legal agreements/contracts is designed to ensure compliance with all legal requirements and regulations and to protect your profession and livelihood by avoiding liability exposure for you as well as for the University's affiliated institutions.

In general, no other employee (physician, scientist, administrator) of the Health Science Center has the authority to legally enter into agreements/contracts of any kind on behalf of the Florida Board of Education, the Florida Board of Governors, the University of Florida Board of Trustees, the Health Science Center, its colleges, its departments/units, its affiliated hospitals, or its other affiliated patient care or managed care organizations.

In order to guard against personal financial risks assumed by signing agreements/contracts without university authorization, you should submit information on each proposed agreement/contract to your designated department administrator, or directly to the Health Science Center Office of Contracts and Related Services, for handling and authorized legal University signatures.

If you have any questions as to the proper signatory for any contractual agreement involving the Health Science Center, please contact Gabriele N. Dupre, J.D., Director, Office of Contracts and Related Services, P.O. Box 112737, telephone 352-273-7007, fax 352-273-7231, or E-mail gnd@ufl.edu. Other contracting information may be found at the Contracts Office website, www.contracts.health.ufl.edu.

DJB/pcp

PI Administrative Time Charge Memo

Jacksonville Physicians, Inc.

653-2 West Eighth Street
P. O. Box 44088
Jacksonville, FL 32231-4008
Tel: (904) 244-3518
Fax: (904) 244-3437

E - MAIL MEMORANDUM

To: Associate Chairmen
From: Nancy D. Frastuer, Chief Executive Officer
Date: July 12, 2005
Subject: Research Grants

There are several changes regarding research grants of which you should be aware. First, at the direction of Drs. Russo and Nuss, the Finance Committee was asked to recommend a method of budgeting and accounting for the administrative time of Principal Investigators and Support Staff in grants where

Administrative Time Charge Memorandum

administrative FTE's are not specifically funded. This situation applies more often to pharmaceutical studies. The Finance Committee's recommendation, which was approved by the Board, was that such grants would be billed a flat 3% against all funds received. This amount would be reflected as revenue on the "home" department to offset a portion of the salary and benefits expense of the PI. This amount would be billed and transferred from the appropriate fund in Gainesville each quarter. It was agreed by the Research Grants Committee that this function will be handled by Rebecca Graham, Post Awards Grant Manager. She will calculate the 3% each quarter based on the system data showing monies received from the sponsors. She will prepare the billing and submit to the Research Coordinators who will then route the billing as normally done with all requests for payment.

The second change involved the approval by the Associate Chairmen of all disbursements from Research Grants. Rather than have the Associate Chair review and sign each individual request for payment, the Research Coordinators will print monthly a report from UFRF or DSR for each grant having activity that month. These will be submitted to the Associate Chairs each month for review and approval. These should be returned to your Research Coordinators who will forward them to Becky Graham. In the event the PI is an Associate Chairman, the reports will be sent to Dr. Nuss for review and approval. In regard to the individual disbursements, these should be forwarded to Teresa Dillinger in the Office of Research Affairs. She will then forward them to Gainesville.

The Research Grants Committee has been actively working on improving the front-end process for registering and billing for clinical services provided to grant patients and for other aspects of Grant Management. Pilot studies are being run to make sure the new processes and forms can work efficiently. Several training sessions have been held to train support staff on these new procedures. It is important that they attend the sessions. We will keep you apprised of these.

Please feel free to call should you have any questions.

Cc: All Principal Investigators, All Research Coordinators
Robert C. Nuss, M.D., Associate Dean and President
Teresa Dillinger, Director, Office of Research, Jacksonville
Becky Graham, Post Awards Grant Manager

IRB Information

Brief (but complete) Instructions for Submitting to the University of FL/Jacksonville IRB

Geared toward investigators submitting to the IRB for the first time...

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 interaction (*Interaction* includes communication or interpersonal contact between investigator and subject.) with the individual, or

(2) identifiable private information (*Private information* 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?

In April of 2003, the “Privacy Rule” went into effect. The Privacy Rule is a new set of Federal regulations contained in the Health Insurance Portability and Accountability Act (HIPAA). The new law affects research in the following areas: privacy requirements; new requirements for activities preparatory to research; new requirements for decedent research; and the requirement to obtain “authorization” from a patient to collect, use and disclose their protected health information (PHI) for the purposes of a research study.

The basic premise of the Privacy Rule is that a patient’s health information belongs to them and in order for you to collect, use or disclose it for research purposes (there is a difference between “research” and “clinical care”), you must obtain their authorization (or “permission”). Patients also have the right to know who their information was disclosed to, which is why in some cases, you will be asked to “track” disclosures of patient information to parties outside the University, SHANDS or VA.

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.

What's Needed for an IRB Submission?

1. First of all, determine whether your project will need to go to the Jacksonville IRB or to the Western IRB:
 - a) Federally funded, investigator or department funded/initiated projects go through the Jacksonville IRB.
 - b) Industry-sponsored clinical trials will need to be sent to the Western IRB. The Western IRB is an independent IRB based in Washington State that serves as one of the University's review boards. If your project meets this criteria, please call the office or access the IRB website (<http://www.hscj.ufl.edu/irb> for instructions. The below information does not necessarily apply to the Western IRB!
2. Once you've determined that the Jacksonville IRB should review your project, there are specific items required for submitting a project to the Jacksonville IRB:

-- **The IRB Introductory Questionnaires (IQ)**

Consists of basic questions about your research. The Jacksonville IRB utilizes an "expedited" process for projects that will expose subjects to minimal risk as well as an "exempt" category. If you believe your project qualifies for an "exemption" from IRB oversight, you should complete the "Exempt IQ". Since expedited and exempt requests are processed administratively through the IRB office, there is no submission deadline for these types of studies. They can be reviewed at any time. It is important to note that all projects involving human subjects must be submitted to the IRB for review. If you believe your project qualifies for an exemption, the IRB must make that determination. Don't risk it! Submit it! Projects that require full board review must adhere to the submission deadlines listed on the IRB webpage.

The PI and the Chair must sign Addendum A of the IRB Questionnaire.

If your study involves ionizing radiation or radioactive materials, it will also have to receive approval from the Radiation Safety Committee before IRB approval may be granted. The same applies for studies that involve gene therapy; Institutional Biosafety approval must be granted before an IRB approval will be granted. See the IRB web page (<http://www.hscj.ufl.edu/irb/>) for instruction on submission to these committees.

- **Proposed Consent Document** - Your proposed consent document must be conformed to the University's template and must be written on an ~~an 8th~~ grade reading level or below. You may obtain ~~this~~ template from the Jacksonville IRB website (<http://www.hscj.ufl.edu/irb/>) or feel free to contact the office directly at ~~(904) 244-9427.~~

- **Protocol** - The Jacksonville IRB office has a protocol template you may wish to use to help write your protocol. It is also available on the website or available by calling the office directly.
 - Any **surveys, advertisements, flyers or questionnaires** associated with the study must be reviewed and approved by the IRB before they can be used. Please include these items (if applicable) in your submission.
 - **Investigator's Brochure**, if applicable.
3. If you need assistance with the above items (or any IRB-related issue) please feel free to contact Sheila Heim, IRB Coordinator at (904) 244-9427.

How Many Copies Should be Submitted?

For a NEW FULL BOARD PROTOCOL:

1 complete hard copy with signatures

1 electronic copy sent to:
IRBsubmission@jax.ufl.edu

For an EXEMPTION REQUEST:

1 copy of cover letter

1 copy of "Short form" introductory questionnaire for exempt studies

1 copy of the formal protocol

1 copy of the data collection form, survey, a advertisement, etc

For an EXPEDITED REVIEW:

1 copy of cover letter

1 copy of cover sheet and introductory questionnaire

1 copy of proposed consent form in the required UF required format

1 copy of formal protocol

1 copy of questionnaires, surveys, flyers, advertisements, if applicable

What are the Submission Deadlines?

1. Please contact the office directly to obtain a list of submission deadlines and meeting dates. The dates are also posted on the IRB web site at <http://www.hscj.ufl.edu/irb>.

Deadlines apply to full board submissions only. Remember, if you are applying for expedited review or an exemption, those types of projects can be submitted at any time. The office is located within the Office of Research Affairs, 9th Floor of Tower II, Suite 9015, and is open from 8am - 5pm, Monday through Friday except University holidays.

Research Administration Basics for Clinical Trials

As an academic medical center, the University of Florida College of Medicine – Jacksonville, is always looking for knowledge about better ways to treat patients. One way this is achieved is by participating in clinical trials.

As an employee of UF, UFJHI, UFJPI, or SHANDS – Jacksonville, you will be involved with participants in clinical trials in some form (e.g., registration, tests/procedures, billing, etc.). You will be a part of the coordination of clinical trials that builds a regional or national reputation for UF&SHANDS and its researchers that brings money into our campus.

It is extremely important that research participants be correctly identified as to which clinical trials they are participating in. Tests or procedures need to be performed at specific times in order to evaluate the effects of the clinical trial on the participants' disease. If tests or procedures are missed or ordered inappropriately it could have adverse effects on the participant.

Additionally, correct identification of research participants is important for billing of tests and procedures. If tests and/or procedures are not registered and/or billed appropriately, the medical center or patient may incur costs that otherwise would be paid for by the sponsor of the clinical trial.

The following frequently asked questions will provide you with detailed information about clinical trials:

- What is a clinical trial?
- What is a research team?
- What is a protocol?
- What are clinical trial phases?
- What protections are there for people who participate in clinical trials?
- What is informed consent?
- Who can participate in a clinical trial?
- Who sponsors clinical trials?
- What happens during a clinical trial?
- What is a placebo?
- What is a control or control group?
- What is a blinded or masked study?
- What are side effects and adverse reactions?
- What are the benefits and risks associated with clinical trials?
- Should participants continue working with their primary health care provider if they participate in a trial?
- Will participants be paid for participating in a clinical trial?

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 Ph.D.) 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 guidelines about who can get into the program. Guidelines 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 of 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.

Start Proposal Procedure

For further help with this procedure, go to <http://www.hr.ufl.edu/training/myUFL/toolkits/myUFLBasics.asp>.

In order to have an account set up for your grant/contract, you will have to enter it into PeopleSoft as follows:

The UF Start Proposal Page is the first step in the grant proposal creation process. The Start Page collects key information for the set up of the proposal and its project(s).

- Log into the system via the myUFL portal (<http://my.ufl.edu>), using your GatorLink user ID and password
- Navigate to Grants > Proposals > UF Start Proposal
- Click the “Add New Proposal” button
- Complete the following fields in the *Proposal Header Information* Section
 - Due Date: Identify date proposal is due by typing in field or using calendar feature
 - Date Type: Use drop-down menu to identify the type of deadline (postmark, internal, etc.)
 - PI: Enter employee ID of Principal Investigator by typing in field or using lookup
 - Short Title: Field is free text; limit 56 characters
 - Long Title: Field is free text
 - Sponsor: Use lookup to identify sponsoring agency
 - Type: Use drop-down menu to identify type of proposal (new, competing continuation, etc.)
 - Purpose: Use lookup to identify purpose of work (research, instruction, clinical trial research, etc.)
 - From and To: Identify dates work will begin and end by typing in field or using calendar feature

- Fill in the following sections only as they apply to your proposal (**NONE OF THESE ARE NEEDED FOR AN INDUSTRY-SPONSORED CLINICAL TRIAL**)
 - Solicitation Information
 - Previous Award
 - Related Proposal
 - Cost Sharing
 - Additional Comments
- Complete the *Mailing Information* section
 - Transmission Code: Use the lookup to choose the abbreviation for the delivery method (such as electronic, overnight, by mail, etc.)
 - Type in mailing information such as Fed Ex#, number of copies, and mailing address. Please Note: This Mailing Instructions field is a required field
- Complete the following fields related to the proposal's project(s) in the *Project* section. Please Note: The proposal saves the administrative information while the project stores monetary information and project specific information, such as resources or subrecipients. A proposal can have multiple projects.
 - Institution ID: Identify whether project is managed out of IFAS, Engineering, or **Main Campus (For Jax select Main Campus)**
 - Primary check box: Every proposal has one primary project. Check if this is the primary project (**You will need to check this box for all new studies**)
 - Department: Type in Department ID or use lookup (**All Jax Depts start with "30"**)
 - Department Contact: If there is a department contact person, enter that person's employee ID here by typing it in or using the lookup (**This is you and if you are not in the list, enter the PI or leave blank**)
 - College (subdivision): Populates automatically based on Department given above
 - Use the Exclude check box only to delete a project

Enter information for all *Professionals* working on the project

- Information for the PI listed in Proposal Header defaults on first line
- To add a professional, click the plus-sign button
- Add information for other professionals:
 - ID: Use lookup to find Employee ID or type directly in field
 - Department ID: Use lookup to identify employee's department
 - Role: Specify the person's project specific role (PI, Co-PI, Key Personnel, etc.)

Enter information related to project *Certifications* (**For clinical trials, you will normally select "No" for all except HIRB**)

- For each of the certifications listed, identify whether the certification is required
 - If a certification is required, choose "yes"; if not, choose "no." If a review is pending, choose "pending."
 - If you choose "yes" under indicator, you must give an assurance number (which is the Jax IRB# not the WIRB assigned #) and expiration date or an exemption number in order to create the proposal

To add another certification click the plus-sign button

- Use the Certification Code lookup to select type of certification. Do not duplicate certification codes. Multiple Conflict of Interest certifications, for example, should be COI1, COI2, etc.

If Facilities and Administrative (F&A) funds will be allocated to professionals, departments, or centers enter that information under *F&A Allocation* section.

Professionals

- %: Enter percent of F&A to be allocated to the professional (**Enter "10"**)
- EmplID: Enter professional's employee ID
- DeptID: Enter professional's department

Departments

- %: Enter percent of F&A to be allocated to the department (Enter “7.5”)
- DeptID: Type in Department ID or use lookup

Center

- %: Enter percent of F&A to be allocated to the center (Enter “7.5”)
- DeptID: Type in center ID or use lookup

Use the plus-sign button to add professionals, departments, or centers

Complete all fields in the *Budget Period Info* section

- Begin Date and End Date: These fields should default from Proposal Header information

To adjust budget periods use plus-sign button and minus-sign button and enter Begin and End

Dates for each period **(For clinical trials, just change to show one line for all years)**

- Target Sponsor Budget: Enter total amount being requested from sponsor. Please Note: If there are multiple budget periods, enter amount being requested per budget period (**This number should be the total of all patient direct costs and IDC—do not put in a per patient amount**)

Complete all fields in *Facility and Admin Set Up* section

- Rate Type: Use lookup to choose type of F&A Rate, such as On-Campus Research, Off-Campus Research, etc. (**This should be “RESON” for On-campus Research for most**)
- FA Base: Use lookup to choose base for calculating F&A (**For industry sponsored clinical trials, choose “TDC”; federal grants should be MTDC.**)
- Budget Rates: **For industry sponsored clinical trials, change the most current rate from 46.5 to 25, i.e. the rate that coincides with the 07/01/2008 date. Leave the other three as is. For all others, the rate should be 46.5%.**

Click the “Create Proposal and Budget Header” button

Write down the system assigned Proposal ID and Project ID numbers

Notes

You must finish the Start Page and create the proposal in one sitting. There is no way to save information and return later.

The UF Start Proposal Page is the first step in the grant proposal creation process. After creating a proposal on the Start Page, you must build the budget using the Budget Line Summary.

Budget Line Summary for the Jax Campus

For Industry sponsored clinical trials, you will only need to show two categories in your budget line summary

1. PERSON which is Personnel – Salary & Benefits
2. OTHER which is all Other Expenses

For all other types of grants, you will need to show all of your categories according to your budget, i.e. personnel, supplies, travel and other.

Here is an example of an industry sponsored trial that includes a budget for \$1,000 per patient (plus 25% IDC) and 10 patients are planned to enter and complete the study. So, that is \$10,000 direct costs plus \$2,500 indirect costs for a total of \$12,500.

PERSON – this will be the PI admin fee for all patients.

Using the above example, the per patient amount will be $\$12,500/10 \times .03 = \37.50 and the total PI admin fee for all patients will be $\$37.50 \times 10 = \375.00 .

OTHER- this is all other direct costs, excluding the PI admin fee.

Using the above example, this would be $\$10,000 - \$375 = \$9,625$.

To Start:

1. The Line # block will already be populated with the number 10; leave as is.
2. The Category block needs to have PERSON listed. Use Lookup (the magnifying glass) to identify the budget category or simply type in the word PERSON.
3. Enter the Personnel amount (375.00) in the Total Direct block Click on the + icon at the end of the row
4. The Line # block will automatically populate with the number 20; leave as is.
5. The Category block needs to have OTHER listed. Use Lookup (the magnifying glass) to identify the budget category or simply type in the word OTHER.

6. Enter the Other expenses amount (9625.00) in the Total Direct block.
7. Click in any other box in order for the total to calculate at the bottom. The Total Budget listed has to match the amount you put on your UF Start Proposal Page for Target Sponsor Budget (unless you have multiple budget periods, which you will not). If they do not match [to the penny], you will not be able to move forward with saving or submitting. Once perfect, click the "Save" button.

Note: You cannot change the category for a line once you have entered it. Instead you will need to delete the row and add a new row.

Pharmacy Services

Pharmacy Services are provided by the SHANDS Jacksonville Department of Pharmacy and may be contacted at:

Clinical Research Services (CRS)/Research Pharmacist
SHANDS Jacksonville Medical Center
Department of Pharmacy
655 W. 8th Street
Jacksonville, FL 32209
Phone: (904) 244-6398
FAX: (904) 244-3499

Clinical Research Service (CRS)

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

Under Joint Commission regulations (Medication Management Standard 7.40), the Department of Pharmacy is responsible for the control, storage, dispensing and disposal of all medications within the organization, including those used for investigational studies. Therefore, all investigational medicines used in hospitalized patients must be stored and dispensed through the hospital pharmacy.

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 (<http://intrashands1.umc.ufl.edu/policyindex/rx.asp>).

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:

- SHANDS Core Policy CP 2.32p – Use of Investigational Drugs (listed on the INFOnet under Policies/SHANDS Healthcare Core Policies/Patient Care; <http://intranet.shands.org/licacc/Intranet/Patient%20Care/CP2.32.pdf>).
- Medication and Pharmacy Procedures (listed on the INFOnet under SHANDS Department search for Department of Pharmacy Toolkit/Medication and Pharmacy Procedures; <http://159.178.96.199/pharmacy/publications/RNORIENT0406.doc>).

- A. If there is any “medication” in the study, whether for standard of care or investigational, the “**Pharmacy Initiation Request for Research**” form (**Part A**) (listed on INFOnet under forms/research/pharmacy initiation request form; http://intrashands1.umc.ufl.edu/employee/forms/Pharm/Pharmacy_Initiation_Request_10-2005.doc) must be completed and submitted to the pharmacy. *Medication* includes any investigational agent(s), FDA-approved medications, over-the-counter medications, herbals, nutritionals, etc.
- 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 SHANDS Jacksonville, including 23-hour observation. CRS will be responsible for the following:
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 SHANDS 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 SHANDS Jacksonville.
- D. If utilizing the CRS for any study, see **Part B** for further instructions.

**SHANDS JACKSONVILLE
UNIVERSITY OF FLORIDA HEALTH SCIENCE CENTER/JACKSONVILLE
PHARMACY INITIATION REQUEST FOR RESEARCH**

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 Clinical Research Service? (**MUST** utilize the Clinical Research Service for all inpatient studies)
 - YES, please complete Items 3 thru 5 below and forward this form along with the following information to the Clinical Research Pharmacist (clinical center/basement):
 - Research protocol
 - Investigator’s brochure (if applicable)
 - IRB approval letter with Consent (this can be forwarded at a later date once approval is obtained)
 - NO, please complete items 3 thru 5 below and submit this form 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.*

3. Protocol Information

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

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

5. 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
	<input type="checkbox"/> Investigational <input type="checkbox"/> IND exempt/FDA approved <input type="checkbox"/> Non-approved indication/dose <input type="checkbox"/> Non-FDA approved (e.g. herbal)	No Yes	No Yes	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other	No Yes (if yes, list procedure)	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other
	<input type="checkbox"/> Investigational <input type="checkbox"/> IND exempt/FDA approved <input type="checkbox"/> Non-approved indication/dose <input type="checkbox"/> Non-FDA approved (e.g. herbal)	No Yes	No Yes	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other	No Yes (if yes, list procedure)	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other
	<input type="checkbox"/> Investigational <input type="checkbox"/> IND exempt/FDA approved <input type="checkbox"/> Non-approved indication/dose <input type="checkbox"/> Non-FDA approved (e.g. herbal)	No Yes	No Yes	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other	No Yes (if yes, list procedure)	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other
	<input type="checkbox"/> Investigational <input type="checkbox"/> IND exempt/FDA approved <input type="checkbox"/> Non-approved indication/dose <input type="checkbox"/> Non-FDA approved (e.g. herbal)	No Yes	No Yes	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other	No Yes (if yes, list procedure)	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other
	<input type="checkbox"/> Investigational <input type="checkbox"/> IND exempt/FDA approved <input type="checkbox"/> Non-approved indication/dose <input type="checkbox"/> Non-FDA approved (e.g. herbal)	No Yes	No Yes	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other	No Yes (if yes, list procedure)	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other
	<input type="checkbox"/> Investigational <input type="checkbox"/> IND exempt/FDA approved <input type="checkbox"/> Non-approved indication/dose <input type="checkbox"/> Non-FDA approved (e.g. herbal)	No Yes	No Yes	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other	No Yes (if yes, list procedure)	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other
	<input type="checkbox"/> Investigational <input type="checkbox"/> IND exempt/FDA approved <input type="checkbox"/> Non-approved indication/dose <input type="checkbox"/> Non-FDA approved (e.g. herbal)	No Yes	No Yes	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other	No Yes (if yes, list procedure)	<input type="checkbox"/> Sponsor <input type="checkbox"/> Department Funds <input type="checkbox"/> Patient/Insurance <input type="checkbox"/> Other

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

Clinical Research - Investigational Drug Service

A. Prior to Starting the Study

1. THE PRINCIPAL INVESTIGATOR OR DELEGATE SHOULD SEND A COPY OF THE PROTOCOL, INVESTIGATOR'S BROCHURE, IRB APPROVAL LETTER AND CONSENT FORM, AND THE PHARMACY INITIATION REQUEST FOR RESEARCH FORM TO THE RESEARCH PHARMACIST.
2. UPON RECEIPT OF THE PROTOCOL, THE RESEARCH PHARMACIST WILL FORWARD A BUDGET PROPOSAL TO THE PRINCIPAL INVESTIGATOR/DELEGATE. UPON REVIEW AND APPROVAL OF THE BUDGET PROPOSAL, THE PRINCIPAL INVESTIGATOR/DELEGATE SHOULD SIGN THE PROPOSAL AND RETURN TO THE RESEARCH PHARMACIST.
3. THE RESEARCH PHARMACIST WILL COORDINATE PROTOCOL SET-UP WITHIN THE PHARMACY, INCLUDING:
 - a. PHARMACIST EDUCATION
 - b. DRUG STORAGE AND DISPENSING PROCEDURES
 - c. COMPUTER ORDER ENTRY/ FINANCE CHARGES – THE MEDICATION WILL BE ADDED TO THE NECESSARY COMPUTER SYSTEM(S), WITH CHARGES ASSESSED APPROPRIATELY (I.E., CHARGE OF \$0.00 WHERE APPLICABLE).
4. STUDY MEDICATION SHOULD BE ORDERED AND SHIPPED TO:

Attention: Research Pharmacist, SHANDS Jacksonville Medical Center,
Department of Pharmacy, 655 West Eighth Street, Jacksonville, FL 32209.
5. THE RESEARCH PHARMACIST SHOULD BE CONTACTED IN ADVANCE TO SET UP ANY SITE VISITS WITH THE SPONSOR REPRESENTATIVE (INCLUDING PRESTUDY OR SITE EVALUATION VISITS AND INITIATION VISITS).

B. Maintenance

1. Any pertinent Protocol Amendments, all revisions to the Investigator's Brochure, and any drug-related correspondence should be forwarded to the Research Pharmacist.
2. The Research Pharmacist should be updated regarding patient enrollment (i.e., patient withdrawal and/or termination of patient enrollment) to ensure appropriate drug inventory.
3. All study monitor visits should be scheduled in advance with the Research Pharmacist.
4. INPATIENT RESEARCH STUDIES
 - a. A physician order MUST be written for the study medication. The order should include the date and time written, patient name, date of birth, unit number, allergies, protocol number, medication name, dose, route, and frequency. The order should also include a statement that informed consent has been obtained. Orders should be forwarded to the Pharmacy per normal procedures unless special arrangements are made in advance with the Research Pharmacist.

- b. If special assistance is required, the Study Coordinator may contact the Research Pharmacist directly.
 - c. Study medication will be prepared and dispensed by Pharmacy Personnel through normal procedures (unless prior arrangements have been made). Each dose will be logged out on the appropriate inventory log in the Pharmacy.
 - d. Study medication will also be entered into the HBO computer pharmacy profile and will print with other routine medications on the medication administration record (MAR) with the comment "For Investigational Use Only".
 - e. Pharmacy invoices will be generated on a quarterly basis and sent to the Principal Investigator/delegate.
5. OUTPATIENT RESEARCH STUDIES
- a. An outpatient prescription MUST be written for the study medication. The order should include the date, patient name, date of birth, allergies, unit number, protocol number, subject number or randomization number, visit number, drug name, strength, route, frequency, quantity, and refill information. Other pertinent information should be included as required for each protocol (i.e., patient weight, IVRS treatment code or bottle #, etc.).
 - b. The Research Pharmacist should be contacted to fill the prescription unless other arrangements have been made. The prescription should be faxed to 244-3499 prior to the dispensing. The original prescription may be given to the Research Pharmacist or Assistant upon delivery of the medication.
 - c. Study medication will be delivered to the patient or study coordinator with appropriate labeling and directions for use. Any study medications returned during the clinic visits should be forwarded to the research pharmacist.
 - d. Pharmacy invoices will be generated on a quarterly basis and sent to the Principal Investigator/delegate.

C. Study Closure

1. The Research Pharmacist should be notified in a timely manner regarding study closure so that close-out procedures may be arranged.
2. Upon final disposition of the study medication (i.e., return to the sponsor representative or destruction), the Pharmacy file will be closed and returned to the Principal Investigator/delegate. The Principal Investigator/delegate should acknowledge receipt of the file by signing the appropriate transfer document(s) and forwarding to the Research Pharmacist.
3. A final invoice for Pharmacy Services will be forwarded to the Principal Investigator/ delegate at the next billing cycle (maintenance fees will continue until study drug is returned to the sponsor representative or destroyed).

TITLE: Investigational Drug Storage, Control and Dispensing in the Ambulatory Clinics

PURPOSE: To Set Standards for the Management of Investigational Agents in the Ambulatory Clinics

POLICY: Investigational Drugs in the Ambulatory Clinics must be stored, controlled and dispensed according to hospital policy, federal regulations, Good Clinical Practices (GCP), protocol-specific guidelines and other regulatory bodies, including the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).

PROCEDURE:

- A. An investigational drug is a drug that has not been approved by the Food and Drug Administration (FDA) for general use and is not commercially available, or one that is already approved by the FDA but is being studied for a different indication or dose or being used as an adjunct for the primary study. An investigational drug can be used only under the supervision of a Principal Investigator (PI) through a protocol approved by the Institutional Review Board.
- B. Storage and Control
 1. Investigational drugs must be separated from other drug stock (i.e., routine floor stock, drug samples, etc.) and stored in a secured and/or locked area. Each storage area must be clearly labeled with the appropriate protocol number.
 2. If a refrigerator or freezer is required, the appliance(s) must be designated for medication only and located in a secured area and/or locked. Daily temperature must be documented on days the clinic is open to patient care.
 3. Access to the investigational drugs must be limited to individuals designated by the PI.
 4. All empty vials/containers, patient returns and/or expired drugs should be quarantined and marked clearly in a secured and/or locked designated area for each protocol until appropriate disposal or return.
 5. At study closure or as designated by the protocol, all empty vials/containers, patient returns, expired drugs and unused drug should be returned to the study sponsor for appropriate disposal. If the sponsor requests on-site destruction, disposal must be in accordance with the Hazardous Waste and Pharmaceutical Disposal Policy (Rx-01-032).
- C. Dispensing
 1. Investigational drugs must be dispensed to subjects under the direct supervision of the PI or designee in accordance with the approved protocol.
 2. The PI or designee should explain the correct use of the investigational drug(s) to each subject and should check, at intervals appropriate to the trial, that each subject is following the instructions properly.
 3. There must be a valid order for the investigational drug documented in the clinic chart and/or Shands Jacksonville medical record.
 4. An accountability log should be maintained for each drug dispensed. The log should include the initials or signature of the preparer/dispenser, date, drug name and strength (or equivalent nomenclature per study), quantity, lot # (or equivalent), expiration date (if available) and the unique code numbers assigned to the investigational drug(s) and trial subjects.

-
5. Prior to dispensing, the investigational drug should be labeled, at a minimum, with the facility name, address, and phone number; patient's full name; physician name; drug name and strength (or equivalent nomenclature per study) and quantity; directions for use in layman's terms; dispense date; expiration date (if available); and the cautionary statement "Caution: Limited by Federal Law to Investigational Use Only."
- D. Each clinic area should conduct and document Quality Assurance on a regular basis according to Policy AMB-04-009 (Medication Maintenance).

References:

- ICH GCP Consolidated Guideline - Part 3.6 Investigational Product(s)
- 21 CFR 312.57 - Recordkeeping and Record Retention
- Title 21 CFR 312.59 - Disposition of Unused Supply of Investigational Drug
- Title 21 CFR 312.6 - Labeling of an Investigational New Drug
-
- Title 21 CFR 312.61 - Control of the Investigational Drug
- Title 21 CFR 312.62 - Investigator Recordkeeping and Record Retention

Policy Rx-01-032

ShandsLackawanna

POLICY NUMBER: Rx-01-032
REVIEW RESPONSIBILITY: Pharmacy
PAGE 1 of 5
REVISED:
REVIEWED: 6/07
APPROVAL: 9/23/02
APPROVED BY: Tiana Hogan, Pharm.D.

TITLE: Hazardous Waste and Pharmaceutical Disposal Policy

PURPOSE:

The purpose of the Hazardous Waste and Pharmaceutical Disposal Policy is to: 1) protect human health and the environment by proper identification, management, handling, and disposal of pharmaceutical or hazardous waste, 2) comply with JCAHO Environment of Care Standard, and 3) comply with all applicable federal, state, and local governmental regulations.

POLICY:

Pharmaceutical waste must be disposed of according to Federal, State and other regulatory standards.

HAZARDOUS WASTE & PHARMACEUTICAL DISPOSAL GUIDELINES:

The following guidelines are designed to identify the types of disposal methods to appropriately discard pharmaceutical waste products (See Appendix A), and associate examples of waste products to be categorized into the method of disposal. There are five types of disposal methods categorized as the following:

I. Biohazard Containers

Any items that have been exposed to or contaminated by bodily fluids are biohazardous materials and are to be placed in a *red* bag labeled "Biohazard" which will alert the environmental services department to treat its contents accordingly.

II. Hazardous Pharmaceutical Waste Containers

Hazardous waste will be placed in *yellow* hazardous waste containers. Once the container is full, environmental services will remove the *yellow* containers from the pharmacy. A transporter from an authorized company will then transport the hazardous waste to an approved facility for hazardous waste disposal. If there is an empty container at the hazardous material then the container will be "triple rinsed" and disposed of in regular trash.

There are three major categories of Hazardous waste:

- 1) Pharmaceuticals and chemicals on the EPA "P" and "U" list such as epinephrine, warfarin and nitroglycerin (See Appendix B).
- 2) Chemotherapy including partial containers and soiled materials.
- 3) Investigational drugs that are not approved by the FDA.

III. Sharps Container

All sharp objects (i.e. all needles, ampules, and broken glass etc.) that have the potential to harm individuals if not handled appropriately will be placed in the appropriate *red* sharp container.

IV. Reverse Distributor

Pharmacy personnel are responsible for quarantining unusable pharmaceutical products in the designated pharmacy area. This includes expired pharmaceuticals, partial vials (non-chemotherapy), loose tablets, capsules and prepacked items.

A reverse distributor will be contacted to remove the unusable pharmaceuticals and determine whether or not the product is considered returnable for credit or waste. The reverse distributor is responsible for proper disposal of non-refundable pharmaceuticals.

V. Regular Trash

General waste (i.e. Paper, labels, empty containers, empty syringes, office supplies, ect.) are discarded in regular trash receptacles. Non-hazardous diluted pharmaceuticals (<1% by volume) can be discarded in regular trash.

Please refer to **attached table** for the disposal methods of hazardous and pharmaceutical waste.

APPENDIX A: DEFINITIONS

A. PHARMACEUTICAL WASTE:

All pharmaceuticals that have been identified as: outdated but not returnable for credit, used in compounding or IV preparation, spilled or broken product no longer reusable for intended purpose, and any items used in cleaning up a spill (vermiculite, paper towels, etc.) must be treated as a waste pharmaceutical, either hazardous or non-hazardous.

B. SOLID WASTE:

Any material that is discarded by either being abandoned, inherently waste-like, or recycled.

C. HAZARDOUS WASTE:

Solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may:

- (a) Cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible, illness; or
- (b) Pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

In order to be considered a hazardous waste, the waste needs to be

- 1) A solid waste
- 2) Listed as a hazardous waste (P and U list), and/or
- 3) Possess hazardous waste characteristics (ignitability, corrosivity, reactivity, or toxicity)

D. HAZARDOUS WASTE CHARACTERISTICS:

- 1) Ignitability – Alcohol content greater than 24%. Examples include: alcohol, ammonia inhalants, amyl nitrate, Anbesol, benzoyl peroxide, benzoin tincture, Cleocin T topical solution, colloid based preparations, Compound W, bronchodilators (Tornalate), methiodate tincture, mouthwash (>24% alcohol), peppermint spirit, Rein A gel, silver nitrate, erythromycin topical solution, and some cough medicines (Nyquil).
- 2) Corrosivity – Highly acidic (pH<2) or highly basic (pH>12.5) compounds. Examples of acids include: glacial acetic acid and liquid phenol. Example of bases include: potassium hydroxide and sodium hydroxide.
- 3) Reactivity – Unstable compounds which include Clinitest and nitroglycerin containing products.
- 4) Toxicity – Compounds that contain organic chemicals or heavy metals, such as chromium, lead, mercury, or cadmium. Examples include: arsenic, barium enemas, chloroform, lindane, mercury, selenium, silver nitrate, thimerosal, and vaccines containing mercury as a preservative.

E. REVERSE DISTRIBUTOR:

A registered and licensed company that the pharmacy will ship outdated pharmaceuticals to and then the company will determine whether the product is deemed a returnable product or a waste.

APPENDIX B: P AND U LIST

EPA has classified various solid wastes as hazardous, including the P and U list. The lists can be found in the Code of Federal Regulations under Title 40, section 261.33.

P List:

Chemicals that are considered to be acutely hazardous because it is fatal to humans or low doses, scientific studies have shown that it has lethal effects on experimental organisms, or it causes serious irreversible or incapacitating illness. The following list includes some examples of P listed pharmaceutical waste and their corresponding waste code:

Epinephrine (Adrenaline)	P042
Nicotine	P073
Nitroglycerin	P081
Physostigmine salicylate	P189
Sodium Azide	P165
Styrene	P168
Warfarin (concentration greater than 0.1%)	P001

U List:

Chemicals that are toxic, but also includes chemicals that display other characteristics such as ignitability or reactivity. The following list includes some examples of U listed pharmaceutical waste and their corresponding waste code:

Acetic acid, salts and esters	U024C
Acetone	U002
Chlorambucil	U035
Chloroform	U044
Cyclophosphamide	U058
Dactinomycin	U059
Dichlorodifluoromethane	U075
Diethylstilbestrol	U089
Formaldehyde	U122
Hexachlorophene	U132
Lindane	U139
Melphalan	U150
Melphar	U151
Mitomycin C	U010
Paraldehyde	U182
Phenacetin	U187
Phenol	U188
Risperidone	U200
Saccharin	U202
Selenium sulfide	U205
Streptozotocin	U206
Trichloroethylene	U121
Uncl. mustard	U237
Warfarin (concentration less than 0.1%)	U248

POLICY NUMBER: Rx-01-032
 REVIEW RESPONSIBILITY: Pharmacy
 PAGE 8 of 5
 REVISED: 2/7/03
 REVIEWED:
 APPROVAL: 9/23/02
 APPROVED BY: Thanh Toggau, Pharm.D.

Pharmaceutical Waste Guidelines and Location of Container Types

Disposal type/area	Color	Example Contents	IV Accessory	Hazardous Prep Area or Pharmacy	Chemoinformatics	Control (Prep and Clinic Control)	MD&P	Control (Lab using)	Parent Comp Areas
Hazardous Bag	Red	Highly toxic contamination							X
Regulate Trash/Regular waste	Clear/White	<ul style="list-style-type: none"> † Paper, labels, empty vials, syringes used for preparation of non-hazardous materials † Non-hazardous diluted drugs (≤3% by volume), such as IV fluids 	X	X	X	X	X	X	X
Reverse Distributor (returned to elevated quarantine area)	Container supplied by vendor	<ul style="list-style-type: none"> † Expired medications in original unopened container † Expired and hazardous (w/ packs, partial vials, loose pills, etc. † Exclude non-hazardous diluted drugs (≤3% per volume) which are to be disposed into regular trash 			X	X			
Contaminated/Spilled (Chemotherapy and/or P&O) drugs	<ol style="list-style-type: none"> 1. Yellow bio-OH 2. White labeled chemotherapy waste bag (one-sterile only) 	<ol style="list-style-type: none"> 1. Sharps, vials, any hazarins were to any form, includes EPA drugs essential prep, and not gloves, gowns, etc. 2. Chemically contaminated and sharps. 		<ol style="list-style-type: none"> 1. X 2. X 	X				(for areas that administer chemos: PSS, SS, L&D), infusion center, (wait clinic)
Sharps Container	Red Sharp Container	Needles, an needles, broken glass	X	X					X

SHANDS Laboratory Guidelines

Clinical Laboratory Guidelines contain important information about the following:

- General Laboratory Policies and Procedures
- Specimen Handling
- Tests with Critical Volume Requirements
- Specimens Requiring Special Collection
- Tests Requiring Scheduling with the Laboratory
- Ordering Supplies
- Panic Values
- Laboratory Personnel Names and Phone Numbers
- Other valuable information

Clinical Laboratory Guidelines are available on the SHANDS INFOnet by clicking the "Department" button and choosing "Laboratory" from the drop down menu.

Reflex Testing

Ordering certain Clinical Laboratory tests may result in the performance of additional tests (at an additional charge). These “reflex tests” are done in circumstances where follow-up is medically indicated or legally required. This may happen automatically or selectively based on the results of the initial test(s). The following list indicates those tests that may generate reflex testing. If you believe that such reflex testing is not indicated for your patient (or not required by the research protocol), please include this information in the “Special Instructions” field on your Research Study Initiation Request Form (RSIRF). Reflex testing protocols are approved by the Medical Executive Committee.

Microbiology/Serology

(4030) Hepatitis B Surface Antigen

If positive the lab orders a Hepatitis B Surface Antigen confirmation by neutralization (4347).

(4100) Immune Deficiency Screen

If positive the lab orders a Western Blot (4412)

(4140) RPR

If positive a titer is done (4150) and if there was never a MHA (micro-hemagglutination, 4110) done for the patient then that is also ordered.

Bacterial cultures

Add on charges for identification and susceptibility testing will apply for most positive cultures.

Core Laboratory (Hematology & Chemistry)

(1060) CBC Screen

If the automated differential does not meet the laboratory criteria for reporting, then a manual differential will be performed.

(2170) Lipid Panel

If the triglyceride is >400 then we will order the Direct LDL (2321) and charge the client.

(2162) Cardiac CK, if the CK is >195, we will order a CKMB 2325 and charge the client.

Blood Banking

(9542) Prenatal Profile

If antibody screen is positive, the following tests may be ordered to identify the antibody:

Antibody panel (5065)

Digitonin elution (5040)

Antibody titer (5300)

Direct Coombs (5080)

Antigen typing (5070)

Antibody neutralization (5055)

Antibody autoabsorption (5030)

(5060) Antibody Screen (see prenatal profile)

If the Antibody Screen is positive on an Inpatient sample, 2 units of red blood cells are provided, including additional testing to provide compatible units.

(5010) ABO/Rh

The following additional tests may be performed to confirm the patient's blood type:

Subgroup type (5330)

Du Variant (5130)

Direct Coombs (5080)

(5435) Antenatal Rh Immune Globulin (Rhig) Evaluation

ABO/Rh (5010)

Antibody Screen (5060)

Note: if the antibody screen is positive, the same tests listed in the Prenatal Profile may be performed to identify the antibody

Fetal screen (5170)

Rhogam (5920)

(5405) Crossmatch

Antigen typing (5070)

(5080) Direct Coombs

If the Direct Coombs is positive, the following tests may be ordered to complete the antibody identification:

See Prenatal Profile

(9504) Cord Blood Workup

If the Direct Coombs is positive, the following tests may be ordered to complete the antibody identification:

See Prenatal Profile

If the ABO or Rh type is inconclusive, the following tests may be ordered to confirm the blood type:

See ABO/Rh

In addition, tests may be ordered on the mother’s blood in order to confirm the diagnosis of Hemolytic Disease of the Newborn.

If necessary, a sample may be sent to the Florida-Georgia Blood Alliance Reference Laboratory for antibody identification. FGBA may perform similar tests or additional procedures in order to provide an accurate identification and compatible blood components.

Pathology

Additional (reflex) tests may be ordered, at the professional discretion of the Pathologist, in order to confirm a diagnosis or provide relevant diagnostic or prognostic information. Reflex tests may include, but are not limited to, special stains and immuno-histochemical markers.

(8105) Cyto-Thin Prep Pap Screen

(8106) Cyto-Thin Prep Pap Smear 1

HPV Reflex Testing	Residual material from Pap specimens that are collected in PreservCyt Solution (ThinPrep) is used for Reflex HPV testing when the result of the pap specimen is ASCUS (Atypical squamous cells of undetermined significance).
HPV Regardless	If HPV testing on a Pap specimen is requested to be performed irrespective of the diagnosis, HPV regardless box on the requisition should be checked. HPV regardless may be ordered in the system in the comment section.

(9141) Breast Profile - includes the following:

9330 Estrogen/Progesterone (charged twice)

9340 Her 2/Neu

9345 Immunoperoxidase (p53)

Plus one of the following depending on the size and/or type of tumor

9322 DNA-Image Analysis

9375 Proliferating Cell (Ki67) or 9321 DNA Cell Cycle Analysis

For Flagler we do only:

9330 Estrogen/Progesterone (charged twice)

9340 Her 2/Neu

Plus one of the following:

9322 DNA-Image Analysis

9375 Proliferating Cell (Ki67) or 9321 DNA Cell Cycle Analysis

(9142) Tumor Profile - includes the following:

9330 Estrogen/Progesterone (charged twice)

9340 Her 2/Neu

9345 Immunoperoxidase (p53)

Plus one of the following depending on the size and/or type of tumor:

9322 DNA-Image Analysis

9375 Proliferating Cell (Ki67) or 9321 DNA Cell Cycle Analysis

(9501) B & T Lymphocyte Panel orders the following:

8837 B & T Lymphocyte Set-up

9010 B & T Lymphocyte - includes the following markers:

CD45, CD3, CD4, CD8, CD19, CD16 (+CD56)

(the above are charged as 6 flow markers - 88180)

(9502) CD4/CD8 Panel orders the following:

1061 CD4/CD8 Set-up

9060 CD4/CD8 ratio & absolute count - includes the following markers:

CD45, CD3, CD4, CD8,

(the above are charged as 4 flow markers - 88180)

(9150) Leukemia Panel - includes the following markers:

Initial panel of markers performed are the following:

CD45, CD14, CD10, CD19, CD5, CD20, CD3, HLA-DR, CD7, CD33, CD34, CD13
(charged as 12 flow markers - 88180)

If no leukemia is determined, the above panel of markers is sufficient.

Acute myelocytic leukemia - add the following to above panel:

CD11C, CD15, CD36, CD41, CD56, CD64, Glycophorin -A

Depending on determination of FAB subtype, special stains may be ordered such as 9310 (Specific esterase), 9355 (Nonspecific esterase), 9380 (Sudan Black B). Usually not all of these are ordered at once.

Acute lymphocytic leukemia - the following markers may be added:

T cell type - add CD1, CD2, CD4, CD8, TdT

B cell type - add TdT

On a rare occasion a leukemia panel may be ordered on a tissue sample, in which case a DNA cell cycle analysis may be done (charge code 9321, CPT code 88182). This may also be ordered, but rarely on other specimens.

Sometimes the physician may be looking for a preleukemic state, myelodysplastic syndrome, or there may be some uncertainty as to the direction to be taken. In these cases, the following panel is run instead of the panel described above:

CD7, CD45, CD14, CD4, CD8, CD3, HLA-DR, CD5, CD19, CD34, CD13, CD33,
Kappa, Lambda

(Charged as 14 flow markers - 88180)

There are a few other markers, which may be added to enhance a diagnosis, such as hairy cell leukemia, or diseases of natural killer cells.

(9150) Lymphoma panel - includes the following markers:

Initial panel run:

CD45, CD14, CD4, CD8, CD3, HLA-DR, CD5, CD19, CD10, CD20, CD38, CD23,
Kappa, Lambda

(charged as 14 flow markers - 88180)

If B cell lymphoma the following markers will be added:

IgA, IgD, IgG, IgM (4 flow markers)

If T cell lymphoma the following markers will be added:

CD1, CD2, CD7

If Burkitts lymphoma is suspected, a TdT will be done.

DNA cell cycle analysis is usually run on all positive lymphomas of tissue samples.

If the diagnosis is multiple myeloma the following panel is run:

CD45, CD14, CD3, CD4, CD5, CD8, CD10, CD19, CD20, CD23, CD38, CD56, Cd138, HLA-DR, , Kappa, Lambda, IgA, IgD, IgG, IgM, DNA cell cycle analysis.
(Charged 20 flow markers plus 9321.)

Radiological Tests Order Codes

DEPT	SIM CDSIM DESC RIPTI ON	FIM CD	REVEN UE DEPTH CPCS	UB92	IP PRICE		
XR	6200	NI-CA HEAD W/CONT	896200	4346	70460	351	2357.00
XR	6201	NI-CA HEAD W/O & W CONT	896201	4346	70470	351	2683.00
XR	6202	NI-CA HEAD W/O CONT	896202	4346	70450	351	2126.00
XR	5115	NI-M3T BRAIN W/CONT	895115	4345	70552	611	2462.00
XR	5116	NI-M3T BRAIN W/O & W CONT	895116	4345	70553	611	2956.00
XR	5117	NI-M3T BRAIN W/O CONT	895117	4345	70551	611	2141.00
XR	5118	NI-M3T HEART FUNC COMP	895118	4345	75554	610	2087.00
XR	5120	NI-M3T HEART W/CONT	895120	4345	75553	610	1982.00
XR	5121	NI-M3T HEART W/O CONT	895121	4345	75552	610	2051.00
XR	5119	NI-M3T MRI HEART FUNC LTD	895119	4345	75555	610	1963.00
XR	5967	NI-NM MPI TOMO(SPECT) SGL	825967	4062	78464	341	2524.00

UF Procedures

AMB-016-01



PROCEDURE NUMBER: AMB-016-01
REVIEW RESPONSIBILITY: VP of Ambulatory Services
REVISED DATE: July 15, 2002
REVIEWED DATE: May, 2003
APPROVAL DATE: June 14, 2002
APPROVED BY: Rita A. James
PAGE 1 of 2

HEALTH SCIENCE CENTER/JACKSONVILLE

TITLE: APPOINTMENT SCHEDULING PROCESS FOR RESEARCH STUDY PATIENTS

PURPOSE: This procedure establishes a standard process for scheduling research patients that will effectively identify an appointment as research.

Scheduling must be completed according to the following procedures for all research patients. If an employee is not sure how to complete any of the following steps, he or she should contact their supervisor for instruction.

DEFINITIONS:

Visit

- Research Visit – A visit that is solely for the purpose of the patient participating in a research study. Service should be billed to and covered by Research Study funds.
- Non-Research “Standard of Care” Procedure/Visit – A patient is participating in a research study, but has a medical condition that is not covered by Research Study and should be billed to patient’s normal payor. Some patients may be seen for research study services and non-research “Standard of Care” services during the same visit.

Registration

- Contract and UFJP Research/Grant Registration – Research visit is billed to Research or Grant study only.
- Register Patient’s Insurance as Primary to Research – Register patient visit with primary insurance as patient’s regular insurance (e.g. – Humana, Avmed, etc.) and secondary to Research information identified on Research Referral Form.
- Shands Research Insurance Plan – Used as secondary payor when visit is billed to patient’s regular insurance as primary payor.

PROCEDURE:

1. A Research Nurse/Coordinator will call the scheduling area to schedule all research appointments.
2. Scheduling personnel will enter “Research Study Patient” and the study Coordinator’s name and pager # in the *appointment comment* field in HBO or IDX for all research appointments.
3. The Research Nurse/Coordinator must complete all fields of the *Research Study Referral Form* and send the completed form to the registering area for each scheduled appointment.



PROCEDURE NUMBER: AMB-016-02
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REVISED DATE: July 15, 2002
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APPROVED BY: Rita A. James
PAGE 1 of 3

HEALTH SCIENCE CENTER/JACKSONVILLE

TITLE: REGISTRATION VISIT FLOW AND BILLING FOR RESEARCH STUDY PATIENTS

PURPOSE: This procedure establishes a standard process for registering research patients to ensure that services are recorded and the appropriate payor is identified.

Registration must be completed according to the following procedures for all research patients. If an employee is not sure how to complete any of the following steps, he or she should contact their supervisor for instruction.

DEFINITIONS:

Visit

- **Research Visit** – A visit that is solely for the purpose of the patient participating in a research study. Service should be billed to and covered by Research Study funds.
- **Non-Research “Standard of Care” Procedure/Visit** – A patient is participating in a research study, but has a medical condition that is not covered by Research Study and should be billed to patient’s normal payor. Some patients may be seen for research study services and non-research “Standard of Care” services during the same visit.

Registration

- **Contract and UFJP Research/Grant Registration** – Research visit is billed to Research or Grant study only.
- **Register Patient’s Insurance as Primary to Research** – Register patient visit with primary insurance as patient’s regular insurance (e.g. – Humana, Avmed, etc.) and secondary to Research account identified on Research Referral Form.
- **Shands Research Insurance Plan** – Used as secondary payor when visit is billed to patient’s regular insurance as primary payor.

PROCEDURE:

1. Registration personnel must review each day’s appointment schedule to identify research visits. The appointment comment should state “research study patient” and the Research Nurse/Coordinator’s name and contact number in the appointment comment field if a patient is scheduled for a research visit.
2. Patients should also present with their Research Study identification card.
3. If a patient presents with their Research Study identification card or if the appointment schedule states that a specific visit is for research, registration personnel must check the *Research Referral Alpha File* at their front desk for a *Research Study Referral Form*.

Forms

Research Study Initiation Request Form

The Research Study Initiation Request Form (RSIRF) must be completed prior to beginning a clinical study. This form involves the Hospital and University in identifying medical services necessary to complete the research protocol. Completion of this form establishes agreed upon pricing for each service. Completion of this form also confirms if unique services can be provided.

List all the lab tests and procedures to be performed at SHANDS under the SHANDS services portion of the form and list all the professional fees associated with the tests/procedures and physician office visits per study protocol under the UFJPI services portion of the form.

Instructions

Fill in the Type of Request

As you are negotiating the study budget with the sponsor, the Research Study Initiation Request Form should be marked as an **“initial budget request”** and submitted to all parties indicated on bottom of page one of the form. Once the budget has been finalized and the study is ready to begin, complete the Research Study Initiation Request Form and mark it as a **“final request”**. The form can be saved to avoid having to duplicate work for a final submission. If there are revisions to the protocol at any point in the duration of the study or if additional services are necessary, the Research Study Initiation Request Form should be resubmitted as an **“amended”** or **“corrected”** form.

Complete all fields in the General Information and Billing Information sections:

- Protocol number
- Protocol title – the complete title
- Abbreviated title – 25 characters max
- Sponsor name
- Principal Investigator name and contract number
- Research Coordinator name and contact numbers
 - Phone, fax, and pager numbers
- Approximate start date, end date, and number of patients to be seen
- Billing information – name and address of financially responsible party

Answer the following billing questions based on the study consent, contract, and IRB approval:

- Will the patient’s insurance be billed primary to the study?
 - Yes – Charges are billed to the patient’s commercial insurance first. The remaining balance, deductible, co-payment, or co-insurance if applicable is then billed to the study.
 - No – The patient’s insurance will not be billed. All charges are the sole responsibility of the study.

- Will the patient's insurance be billed primary to the study in case of an adverse event related to the study?
 - Yes – Charges due to an adverse event are billed to the patient's commercial insurance first. The remaining balance, deductible, co-payment, or co-insurance if applicable is then billed to the study.
 - No – The patient's insurance will not be billed. All charges due to an adverse event are the sole responsibility of the study.
- Will the study pay for an Adverse Event not covered by insurance?
 - Yes – If the insurance claim is denied or the patient does not have insurance, charges due to an adverse event are billed to the study.
 - No – All charges due to an adverse event are billed to the patient.
- Will the patient require a bed?
 - Yes – the patient will be admitted solely for research purposes either as an in-patient, or for observation or ambulatory surgery.
 - No – all research services are performed strictly on an outpatient basis.

Answer the following Radiology questions:

- Are Radiological services needed (CT, MR, NM, Angiography, PET, or any other special imaging)?
 - Yes – Forward imaging protocols to Anne Shumway, Radiology Research Office for review.
- Are Interpretations or other UF Radiologist services needed?
 - Please list required interpretive services on page 3.
- Does this project require nursing, coordinating, 3D post-processing, CD burning, or other services from Radiology Research personnel?
 - Please list required additional services on page 3.

Complete Page 2 – Shands Technical Services

- Provide PI name and IRB number at the top of page 2
- List required technical services including the test description, SIM code, and price in the spaces provided. Use the link below to access the hospital fee schedule – <f:/common/research studies/2008 research fee schedule>
 - Provide the test description and CPT code for services not listed in the fee schedule.
- Provide special instructions, if any, in the box provided.

Shands will verify fees, assign an account number and contract code (and/or insurance plan number when applicable), sign and date the form, and fax to the Research Coordinator or other contact person listed on page one.

You will receive from SHANDS Financial Services a contract (RES) code number to be used for the duration of the study along with a confirmation of fees for tests/procedures performed. At the beginning of each SHANDS fiscal year, the fees will be adjusted to reflect the then current research fee schedule as appropriate. NIH grants adjustments will be at the lesser of a 3% increase or the SHANDS annual overall price increase. It is important to keep in mind the adjustments to these fees as the budget negotiations are taking place.

Complete Page 3 – UF Professional Services

- Provide PI name and IRB number at top of page 3
- List required professional services including the test description, CPT code, B Code, and price in the spaces provided.
- Provide special instructions, if any, in the box provided.

UFJP will complete any blank procedure codes, B codes, or research prices. The Director of Reimbursement will approve fees, sign, and fax to Research Coordinator or other contact person listed on page one.

The Grants Manager will review the submitted form and obtain signature authority from the UFJP Director of Reimbursement to authorize the stated UFJP research prices. The Director of Reimbursement will complete any UFJP prices left blank. A copy of the signed form will then be returned to the coordinator.

Note: The Research Study Initiation Request Form will not be distributed to the Business Group Managers until a final copy is received.

RESEARCH STUDY INITIATION REQUEST FORM

Please attach a copy of the Schedule of Events with this form.
 This form must be completed and approved prior to the start of the study.
 For detailed instructions, please refer to the Research Manual

Initial Budget Request

Today's Date: _____ Protocol Number: _____

Principal Investigator: _____

Sponsor Name: _____

Protocol Title: _____

Abbreviated Title
(25 Character Max) _____

Research Coordinator _____

Phone # _____ Fax # _____ Pager # _____

Star. Date _____ End Date _____ Target # Pts. _____

Billing Information	
Send Invoices To: _____	

	No Yes
Will the patient's insurance be billed primary to the study?	<input type="checkbox"/> <input type="checkbox"/>
Will the patient's insurance be billed for an adverse event related to the study?	<input type="checkbox"/> <input type="checkbox"/>
Will the study pay for an adverse event not covered by insurance?	<input type="checkbox"/> <input type="checkbox"/>
Will the patient require a bed for Observation or Ambulatory Surgery?	<input type="checkbox"/> <input type="checkbox"/>
Will the patient be admitted for study related In-patient procedures?	<input type="checkbox"/> <input type="checkbox"/>
Diagnosis: _____	
Procedures _____	

	No	Yes	
Will investigational device charges be billed to the patient's insurance?	<input type="checkbox"/>	<input type="checkbox"/>	Please provide copy of CMS approval letter with Investigation Device Exemption (IDE) number
Does this project require Pharmacy services?	<input type="checkbox"/>	<input type="checkbox"/>	Please complete the Pharmacy Initiation form and send to Research Pharmacist, Bsmi, CC.
Does this project require Radiological services CT, MR, NM, PET, or Angiography?	<input type="checkbox"/>	<input type="checkbox"/>	Please send imaging protocols and copy of RSIRF to Anne Shumway, Radiology Research 2 nd Fl., Pavilion.
Does this project require Pathology services: immunohistochemistry, flow cytometry, biopsy, special stains, or molecular testing?	<input type="checkbox"/>	<input type="checkbox"/>	Please send Pathology protocols and copy of RSIRF to Becky Garrison, Clinical Laboratory, 1 st Fl, CC.

Distribution: Stands Patient Financial Services - Date and UF Audit Services - Date

Principal Investigator:		Protocol Number	
-------------------------	--	-----------------	--

SHANDS Technical Services

DESCRIPTION	CPT CODE	SIM CODE	PRICE
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30			

Special Instructions: (please indicate any deviations from established policy and procedure, here. Attach additional pages if necessary.)

THIS SECTION TO BE COMPLETED BY SHANDS

Account No.	Contract Code	Insurance Plan
-------------	---------------	----------------

Approval Signature _____ Date _____
(PFS Director or Designee)

Principal Investigator:		Protocol Number:	
-------------------------	--	------------------	--

UF Professional Services			
	DESCRIPTION	CPT CODE	B CODE / PRICE
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Special Instructions: (please indicate any deviations from established policy and procedure, here. Attach additional pages if necessary.)
 A of FORMTEXT

THIS SECTION TO BE COMPLETED BY UFJP

Approval Signature: _____ Date: _____
 (Director of Reimbursement)

Contract Billing Registration Form



Contract Billing Registration Form

TAB FROM FIELD TO FIELD AND TYPE REQUIRED INFORMATION IN SHADED AREA.

PLEASE FAX THIS FORM TO THE LABORATORY AT 244-2898 TO OBTAIN PATIENT ACCOUNT #.

Patient Name: _____

Patient Unit #: _____ Pt. Room # (if applicable): _____

Name of Study: _____ Contract Code: _____

Research Coordinator: Name: _____

Extension: _____ Fax #: _____

Pager: _____

CONTRACT ACCOUNT NUMBER: _____

NOTE: Please call the Laboratory at ext. 4-6047 prior to faxing form to ensure prompt registration.

Research Patient Referral Form

RESEARCH PATIENT REFERRAL FORM

Coordinator Name
Ext #

Pager #

PI Name
UF IRB #

PATIENT INFORMATION

Patient Name
DOB
Street Address
City/State

Unit#
Social Security #

Race
Home Phone
M/F
Zip Code

HOSPITAL REGISTRATION

Please use the generic Research Insurance Plan number 19-1840 and free text the following information:

Research Study Name (Group Name)

Contact Name (Mail to Person)

Research Department (Mail to Company)

Campus Address (Address Line 1)

Patient has Commercial Insurance
(Please provide proof of insurance)

Commercial Insurance is Primary to Research

UFJP REGISTRATION

UFJP Research/Grant Registration

Case #

Billing Information (if case number is not assigned)

Patient has Commercial Insurance
(Please provide proof of insurance)

Commercial Insurance is Primary to Research

PHYSICIAN'S ORDERS

Primary Diagnosis

ICD9 Code

Secondary Diagnosis

ICD9 Code

Tertiary Diagnosis

ICD9 Code

Required Tests (Please Include Diagnosis)

Order Code	Description of Service	Service Date	Diag Code	Order Code	Description of Service	Service Date	Diag Code

Physician's Signature _____ Physician # _____ Date _____

Comments: _____

Charge Correction Request Form

Guidelines

Use the Charge Correction Request form to request contract late charges and late credits. Since Patient Financial Services (PFS) is not a revenue-generating department, all contract billing transactions must be properly documented. Incomplete or unsigned forms will not be processed.

- Indicate type of request – charge or credit – by checking the appropriate box.
- Provide the contract account information (contract name and contract code) and patient account information (patient name and patient account number).
- Provide the transaction details including service date, order code, description of service, diagnosis (for in-patients), quantity, and price.
- Indicate if the charge(s) or credit(s) should be moved to an in-patient account by checking yes or no (bottom of page). Provide the patient's medical record number in the space provided.
- Indicate if the charge(s) or credit(s) should be moved to another contract account by checking yes or no (bottom of page). Provide the contract code in the space provided.

Note: Late charges and credits posted by PFS after the bill cycle date will appear on the following month's billing statement.

Radiology Research Initiation Checklist

Additional Contacts

SHANDS/UFJHI

Appointment Scheduling

Laboratory

Contract Account	1 st Floor CC	244-6047
Outpatient Lab	1 st Floor CC	244-6047
Draw Area	2 nd Floor Fac.Clinic	244-3306

Radiology

Diagnostic/Routine	2 nd Floor CC Pavilion	244-7233 or 244-7244 244-7233 or 244-7244 244-1700 (same day service only)
CT/MRA/MRI Scans	1 st Floor CC	244-7233 or 244-7244
Ultrasound	2 nd Floor CC	244-7233 or 244-7244
MRI/Towers	Jefferson Street Bldg.	244-7233 or 244-7244
Breast Center	Tower II/4 th Floor	244-9400

Cardiology

EKG-Outpatient	5 th Floor ACC	244-4205
EKG-Inpatient	CC (Available 24/7) Pavilion	Pgr. 498-0258 or 498-0259 M-F 7am-3pm; Pgr. 393-6262 After Hours; Pgr. 393-3641
Stress Test	5 th Floor ACC	244-4205
Echo	5 th Floor ACC	244-4205
Holter Monitor	5 th Floor ACC	244-4205

Patient Financial Services

Manager	Queen King	244-1877	queen.king@jax.ufl.edu
Coordinator	Darin Morse	244-1911	darin.morse@jax.ufl.edu

UFJP

Business Group

Directors

Director of the Business Groups	Barry Hamel	43550
Director of CDQ	Wendey Landkrohn	43603
Director of Information Systems	Maribeth Anderson	43630
Director of Support Services	Katherine Isaacs	493-0599

Managers

<u>Group Number</u>	<u>Name</u>	<u>Phone Number</u>
1	Pam Schirkofsky	43529
2	Terri Schnoering	43543
3	Becky Osborne	43650
4	Kelly Britt	43949
5	Cheryl Barber	43791
6	Robert Wood	48095
7	Janis Mott	43426
8	Amy Sherman	43536
9	Kay Strickland	44730
10	Susie Wheeler	45947
11	Alan Schnoering	43640
12	Efferem Williams	45021

Team Leads

<u>Group Number</u>	<u>Name</u>	<u>Phone Number</u>
1	Matise Allen	43565
2	Angela LaVille	48146
3	Lynda Vining	43604
4	Sheryl McLennon	44970
4	Robbi Green	48085
5	Teresa Eason	45033
5	Paula Long	45538
6	Rafayette Price	43588
7	Toni Kallas	43680
7	Sharon Flemmings	43680
8	Lori McDonald	43620
9	Juanna Gifford	47711
9	Emily Smith	47640
10	April Smith	43442
10	Karen Morgan	43599
11	Wesley Thomas	48175
12	Sandra Harper	43560

Audit Services

Grants Manager Andy Wojcicki 244-3841 andrew.wojcicki@jax.ufl.edu

4th Floor LRC, Audit Services
653-1 W. 8th Street
Faculty Clinic Bldg
Jacksonville, FL 32209

Faculty Clinic Registration

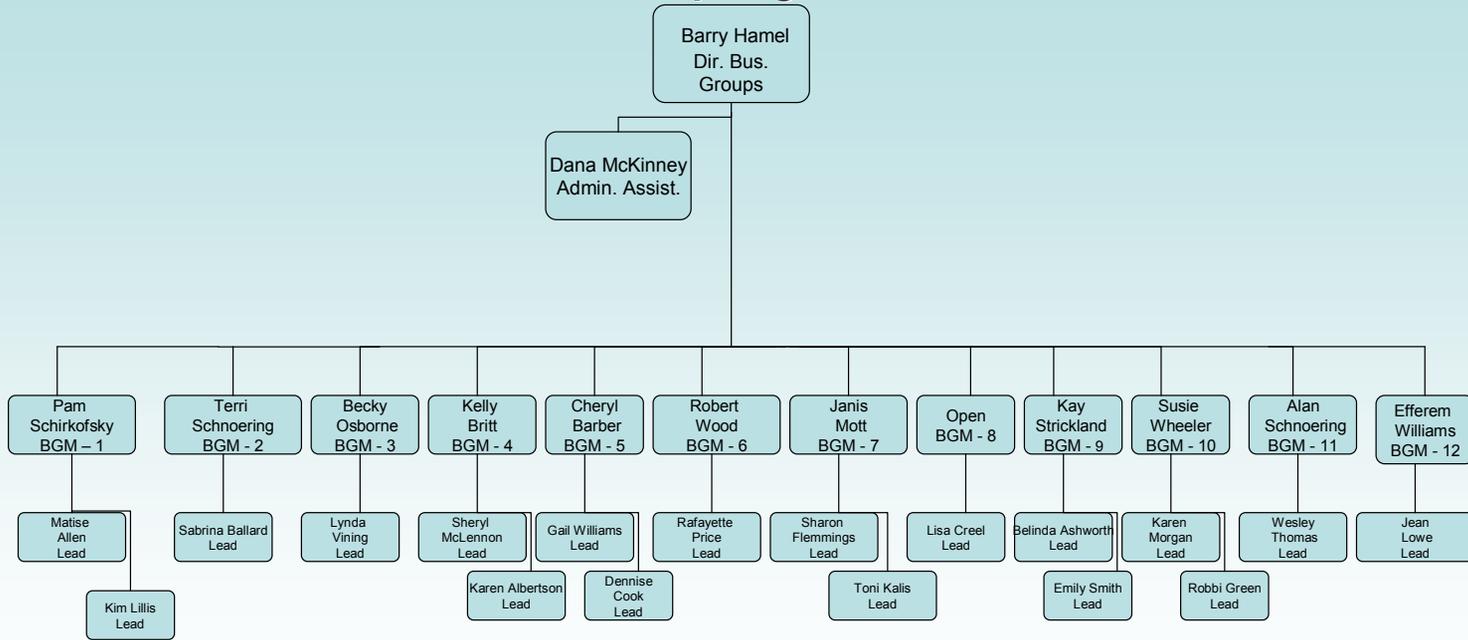
Manager Patricia Kendrick 244-3579 patricia.Kendrick@jax.ufl.edu

Faculty Wage Allocation

Barbara Conger 244-9532 barbara.conger@jax.ufl.edu

University Of Florida

Business Group Organization Chart



Glossary

Terms

This glossary of terms is compiled to aid persons in research administration. Note that generally one definition is provided. Federal agencies often provide definitions within their own guidelines. This glossary is not intended to override agency specific definitions.

Accrued expenditures means the charges incurred by the recipient during a given period requiring the provision of funds for: (1) goods and other tangible property received; (2) services performed by employees, contractors sub-recipients, and other payees; and, (3) other amounts becoming owed under programs for which no current services or performance is required.

Source: Office of Management and Budget Circular A-110

Accrued income means the sum of: (1) earnings during a given period from (i) services performed by the recipient, and (ii) goods and other tangible property delivered to purchasers, and (2) amounts becoming owed to the recipient for which no current services or performance is required by the recipient.

Source: Office of Management and Budget Circular A-110

Acquisition cost of equipment means the net invoice price of the equipment, including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Other charges, such as the cost of installation, transportation, taxes, duty or protective in-transit insurance, shall be included or excluded from the unit acquisition cost in accordance with the recipient's regular accounting practices.

Source: Office of Management and Budget Circular A-110

Advance means a payment made by Treasury check or other appropriate payment mechanism to a recipient upon its request either before outlays are made by the recipient or through the use of predetermined payment schedules.

Source: Office of Management and Budget Circular A-110

Allocation means the process of assigning a cost, or a group of costs, to one or more cost objective, in reasonable and realistic proportion to the benefit provided or other equitable relationship.

Source: Office of Management and Budget Circular A-21

Animal means any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

Source: Public Health Service on Humane Care and Use of Laboratory Animals [Public Law 99-158]

Animal Facility means, any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal, confinement, transport, maintenance, breeding, or experiments, inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

Source: Public Health Service on Humane Care and Use of Laboratory Animals [Public Law 99-158]

Award means financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements in the form of money or property in lieu of money, by the Federal Government to an eligible recipient. The term does not include: technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; and contracts which are required to be entered into and administered under procurement laws and regulations.

Source: Office of Management and Budget Circular A-110

Budget period means the intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

Source: NIH Grants Policy Statement 2001

Cash contributions means the recipient's cash outlay, including the outlay of money contributed to the recipient by third parties.

Source: Office of Management and Budget Circular A-110

Closeout means the process by which a Federal awarding agency determines that all applicable administrative actions and all required work of the award have been completed by the recipient and Federal awarding agency.

Source: Office of Management and Budget Circular A-110

Consortium Agreement means a collaborative arrangement in support of a research project in which some portion of the programmatic activity is carried out through a formalized agreement between the grantee and one or more other organizations that are separate legal entities administratively independent of the grantee.

Source: NIH Grants Policy Statement 2001

Co-Investigator - An individual involved with the principal investigator in the scientific development or execution of a project. The co-investigator may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered “key personnel.” The designation of a co-investigator, if applicable, does not affect the principal investigator’s roles and responsibilities as specified in this policy statement.

Source: NIH Grants Policy Statement 2001

Contract means a procurement contract under an award or sub-award, and a procurement subcontract under a recipient’s or sub-recipient’s contract.

Source: Office of Management and Budget Circular A-110

Cooperative Agreement means a financial assistance mechanism used when substantial Federal Programmatic involvement with the recipient during performance is anticipated by the NIH Institute or Center.

Source: Office of Management and Budget Circular A-110

Cost Reimbursable Contract Type - Contracts that provide for payment of allowable incurred costs to the extent prescribed in the contract. There is an estimate of the total costs for the purpose of obligating funds and a ceiling that the vendor may not exceed (except at its own risk) without approval of the contracting officer.

Source: NIH – NITAAC Glossary

Cost sharing or matching means that portion of project or program costs not borne by the Federal Government.

Source: Office of Management and Budget Circular A-110

Date of completion means the date on which all work under an award is completed or the date on the award document, or any supplement or amendment thereto, on which Federal sponsorship ends.

Source: Office of Management and Budget Circular A-110

Direct costs are those costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.

Source: Office of Management and Budget Circular A-21

Disallowed costs means those charges to an award that the Federal Awarding agency determines to be unallowable, in accordance with the applicable Federal cost principles or other terms and conditions contained in the award.

Source: Office of Management and Budget Circular A-110

Equipment means tangible nonexpendable personal property including exempt property charged directly to the award having a useful life of more than one year and an acquisition cost of \$5000 or more per unit. However, consistent with recipient policy, lower limits may be established.

Source: Office of Management and Budget Circular A-110

Excess property means property under the control of any Federal awarding agency that, as determined by the head thereof is no longer required for its needs or the discharge of its responsibilities.

Source: Office of Management and Budget Circular A-110

Exempt property means tangible personal property acquitted in whole or in part with Federal funds, where the Federal awarding agency has statutory authority to vest title in the recipient without further obligation to the Federal Government. An example of exempt property authority is obtained in the Federal Grant and Cooperative Agreement Act (31 U.S.C. 6306), for property acquired under an award to conduct basic or applied research by a non-profit institution of higher education or non-profit organization whose principal purpose is conducting scientific research.

Source: Office of Management and Budget Circular A-110

Expanded authorities means the operating authorities provided to grantees under certain research grant mechanisms that waive the requirement for NIH prior approval for specified actions.

Source: NIH Grants Policy Statement 2001

Expiration Date means the date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or “completion date.”

Source: NIH Grants Policy Statement 2001

Facilities and administrative (F&A) costs means costs that are incurred for common or joint objectives and, therefore, cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity.

Source: Office of Management and Budget Circular A-21

Federal awarding agency means the Federal agency that provides an award to the recipient.

Source: Office of Management and Budget Circular A-110

Federal funds authorized means the total amount of Federal funds obligated by the Federal Government for use by the recipient. This amount may include by authorized carryover of un-obligated funds from prior funding periods when permitted by agency regulations or agency implementing instructions.

Source: Office of Management and Budget Circular A-110

Federal share of real property, equipment, or supplies means that percentage of the property's acquisition costs and any improvement expenditures paid with Federal funds.

Source: Office of Management and Budget Circular A-110

Firm Fixed Price Contract Type (FFP) means a firm fixed price contract provides for a firm price that is not subject to any adjustment on the basis of the prime contractor's cost experience in performing the contract. This contract type places maximum risk on the vendor. It also provides maximum incentive for the vendor to control cost and perform effectively.

Source: NIH – NITAAC Glossary

Fellowship is generally an amount paid for the benefit of an individual to aid in the pursuit of study or research.

Source: Office of Management and Budget Circular A-110

Funding period means the period of time when Federal funding is available for obligation by the recipient.

Source: Office of Management and Budget Circular A-110

Grant means a financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH Institute or Center anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Source: NIH Grants Policy Statement 2001

Human subject means, a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Source: Title 45 code of Federal Regulation Part 46 Protection of Human Subjects

In kind means 1) with produce or commodities rather than with money: pay in kind. 2) in the same manner or with an equivalent: returned the slight in kind.

Source: The American Heritage® Dictionary of the English Language, Fourth Edition

Indirect cost – see facilities and administrative costs

Institutional Base Salary - The annual compensation paid by an applicant/grantee organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Source: NIH Grants Policy Statement 2001

Intangible property and debt instruments means, but is not limited to, trademarks, copyrights, patents and patent applications and such property as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership, whether considered tangible or intangible.

Source: Office of Management and Budget Circular A-110

Intellectual property means a product of the intellect that has commercial value, including copyrighted property such as literary or artistic works, and ideational property, such as patents, appellations of origin, business methods, and industrial processes.

Source: The American Heritage® Dictionary of the English Language, Fourth Edition

Key personnel – Individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project. The principal investigator and collaborators are included in this category.

Source: NIH Grants Policy Statement 2001

Modular application – A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

Source: NIH Grants Policy Statement 2001

Nonresident Alien is an alien (not a U.S. citizen) who does not meet one of the two tests described in IRS publication 519 under Resident Alien i.e., the Green Card test or the Substantial Presence Test.

Notice of Grant Award – The legally binding document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.

Source: NIH Grants Policy Statement 2001

Obligations means the amounts of orders placed, contracts and grants awarded, services received and similar transactions during a given period that require payment by the recipient during the same or a future period.

Source: Office of Management and Budget Circular A-110

Outlays or expenditures means charges made to the project or program. They may be reported on a cash or accrual basis. For reports prepared on a cash basis, outlays are the sum of cash disbursements for direct charges for goods and services, the amount of indirect expense charged, the value of third party in-kind contributions applied and the amount of cash advances and payments made to sub-recipients. For reports prepared on an accrual basis, outlays are the sum of cash disbursements for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the net increase (or decrease) in the amounts owed by the recipient for goods and other property received, for services performed by employees, contractors, sub-recipients and other payees and other amounts becoming owed under programs for which no current services or performance are required.

Source: Office of Management and Budget Circular A-110

Personal property means property of any kind except real property. It may be tangible, having physical existence, or intangible, having no physical existence, such as copyrights, patents, or securities.

Source: Office of Management and Budget Circular A-110

Principal Investigator Administrative Time (3%) means time allocated by the Principal Investigator to apply for, manage, monitor, review, and conclude a sponsored project. Administrative time does not include clinical effort which should be billed for as an office visit / consultation or as a specific procedure.

Principal Investigator/Program Director/Project Director – An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee for the proper conduct of the project or activity.

Source: NIH Grants Policy Statement 2001

Prior approval means written approval by an authorized official evidencing prior consent.

Source: Office of Management and Budget Circular A-110

Program income means gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (see exclusions in paragraphs _____. 24 [e] and [h].3). Program income includes, but is not limited to, income from fees for services performed, the use or rental of real or personal property acquired under federally-funded projects, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and interest on loans made with award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal awarding agency regulations or the terms and conditions of the award, program income does not include the receipt of principal on loans, rebates, credits, discounts, etc. or interest earned on any of them.

Source: Office of Management and Budget Circular A-110

Project costs means all allowable costs, as set forth in the applicable Federal cost principles, incurred by a recipient and the value of the contributions made by third parties in accomplishing the objectives of the award during the project period.

Source: Office of Management and Budget Circular A-110

Project period means the period established in the award document during which Federal sponsorship begins and ends.

Source: Office of Management and Budget Circular A-110

Property means, unless otherwise stated, real property, equipment, intangible property and debt instruments.

Source: Office of Management and Budget Circular A-110

Real property means land, including land improvements, structures and appurtenances thereto, but excludes movable machinery and equipment.

Source: Office of Management and Budget Circular A-110

Recipient means an organization receiving financial assistance directly from Federal awarding agencies to carry out a project or program. The term includes public and private institutions of higher education, public and private hospitals, and other quasi-public and private non-profit organizations such as but not limited to, community action agencies, research institutes, educational associations, and health centers. The term may include commercial organizations, foreign or international organizations (such as agencies of the United Nations) which are recipients, sub-recipients, or contractors or subcontractors of recipients or sub-recipients at the discretion of the Federal awarding agency. The term does not include government-owned contractor-operated facilities or research centers providing continued support for mission-oriented, large-scale

programs that are government-owned or controlled, or are designated as federally-funded research and development centers.

Source: Office of Management and Budget Circular A-110

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Source: Title 45 code of Federal Regulations Part 46 Protection of Human Subjects

Research and development means all research activities, both basic and applied, and all development activities that are supported at universities, colleges, and other non-profit institutions. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function.

Source: Office of Management and Budget Circular A-110

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Source: NIH Grants Policy statement 2001

Scholarship is generally an amount paid for the benefit of a student at an educational institution to aid in the pursuit of studies. The student may be either an undergraduate or graduate.

Source: Internal Revenue Service Publication 520

Small awards means a grant or cooperative agreement not exceeding the small purchase threshold fixed at 41 U.S.C. 403 (11) (currently \$25,000).

Source: Office of Management and Budget Circular A-110

Stipend means a fixed and regular payment, such as a salary for services rendered or an allowance.

Source: The American Heritage® Dictionary of the English Language, Fourth Edition

Note: some agencies have specific definitions applicable to their own regulations; e.g.,.

[Stipend: A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

Source: NIH Grants Policy statement 2001]

Sub-award means an award of financial assistance in the form of money, or property in lieu of money, made under an award by a recipient to an eligible sub-recipient or by a sub-recipient to a lower tier sub-recipient. The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include procurement of goods and services nor does it include any form of assistance which is excluded from the definition of "award" in paragraph (e).

Source: Office of Management and Budget Circular A-110

Sub-recipient means the legal entity to which a sub-award is made and which is accountable to the recipient for the use of the funds provided. The term may include foreign or international organizations (such as agencies of the United Nations) at the discretion of the Federal awarding agency.

Source: Office of Management and Budget Circular A-110

Supplies means all personal property excluding equipment, intangible property, and debt instruments as defined in this section and inventions of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement ("subject inventions"), as defined in 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements."

Source: Office of Management and Budget Circular A-110

Suspension means an action by a Federal awarding agency that temporarily withdraws Federal sponsorship under an award, pending corrective action by the recipient or pending a decision to terminate the award by the Federal awarding agency. Suspension of an award is a separate action from suspension under Federal agency regulations implementing E.O.s 12549 and 12689, "Debarment and Suspension."

Source: Office of Management and Budget Circular A-110

Termination means the cancellation of Federal sponsorship, in whole or in part, under an agreement at any time prior to the date of completion.

Source: Office of Management and Budget Circular A-110

Third party in-kind contributions means the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefiting and specifically identifiable to the project or program.

Source: Office of Management and Budget Circular A-110

Un-liquidated obligations, for financial reports prepared on a cash basis, means the amount of obligations incurred by the recipient that have not been paid. For reports prepared on an accrued expenditure basis, they represent the amount of obligations incurred by the recipient for which an outlay has not been recorded.

Source: Office of Management and Budget Circular A-110

Un-obligated balance means the portion of the funds authorized by the federal awarding agency that has not been obligated by the recipient and is determined by deducting the cumulative obligations from the cumulative funds authorized.

Source: Office of Management and Budget Circular A-110

Un-recovered indirect cost means the difference between the amount awarded and the amount which could have been awarded under the recipient's approved negotiated indirect cost rate.

Source: Office of Management and Budget Circular A-110

Un-related business income is the income from a trade or business that is regularly carried on by an exempt organization and that is not substantially related to the performance by the organization of its exempt purpose or function, except that the organization uses the profits derived from this activity.

Source: Internal Revenue Publication 598

Voluntary un-committed cost sharing is defined, for the purpose of Circular OMB A-21 as university faculty (including senior researchers) effort that is over and above that which is committed and budgeted for in a sponsored agreement.

Source: Office of Management and Budget Memorandum M-01-06

Working capital advance means a procedure where by funds are advanced to the recipient to cover its estimated disbursement needs for a given initial period.

Source: Office of Management and Budget Circular A-110

Acronyms and Abbreviations

AEF	Academic Enrichment Fund
AFOSR	Air Force Office of Sponsored Research
C & G	Contracts and Grants
C/S	Cost Sharing
CAS	Cost Accounting Standards
CDA	Confidentiality / Non-Disclosure Agreement
CMS	Children's Medical Services
CRF	Case Report Form
CRS	Clinical Research Services (Jacksonville College of Pharmacy)
CTA	Clinical Trial Agreement
DL	Departmental Ledger
DSR	Division of Sponsored Research
EIES	Engineering & Industrial Experimental Station
EO	Expansion Option
EPA	Environmental Protection Agency
F & A	Facilities and Administration
F & A	Finance and Accounting
FDP	Federal Demonstration Project
FL DCF	Florida Department of Children and Families
FL DEA	Florida Department of Elder Affairs
FL DEP	Florida Department of Environmental Protection
FL DJJ	Florida Department of Juvenile Justice
FL DOE	Florida Department of Education
FL DOH	Florida Department of Health
FL DOI	Florida Department of Interior
FL DOS	Florida Department of State
FL DOT	Florida Department of Transportation
FLAIR	Florida Accounting Information Resource (was SAMAS)
FSR	Financial Status Report
GI File	Grant Information File (SACA application)
GIF	Grant Information File (SACA application)
GT	Grant Type
HUD	US Department of Housing & Urban Development
I.D.	Inter-Departmental (Expense Refunds, Invoices, Requisitions)
IDC	Indirect Cost (also known as Overhead)
IFAS	Institute of Food & Agricultural Science
IRB	Institutional Review Board
IS	Information Services
JT	Journal Transfer
LOC	Letter of Credit
MG&G	Miscellaneous Gifts & Grants
MOP	Method of Payment
MTDC	Modified Total Direct Costs
NASA	National Aeronautics & Space Administration

NEH	National Endowment for the Humanities
NERDC	NERCICS Application/Dean's Menu
NIH	National Institutes of Health
NOA (Agency)	Notice of Award
NOA (DSR)	Notification of Award/Acceptance
NSF	National Science Foundation
O/H	Overhead (also known as IDC)
OCO	Operating Capital Outlay (equipment)
OFS	Original Fund Source
OPS	Other Personnel Services
ORA	Office of Research Affairs (Jacksonville)
P.I.	Principal Investigator
P.O.	Purchase Order
PHS	Public Health Service
RFA	Request for Application
RFP	Request for Proposal
RGP	Research & Graduate Programs (formerly ORTGE)
SACA	State system for accessing accounting information
SACN	State system for accessing Natural information
SAMAS	State Automated Management Accounting Subsystem (now known as FLAIR)
TAR	Travel Authorization Request
TDC	Total Direct Cost
TR20	Transaction 20 (Allotment Worksheet/Transfer for budget release)
UFRF	University of Florida Research Foundation
US DED	US Department of Education
US DER	US Department of Environmental Regulations
US DHHS	US Department of Health & Human Services
US DOC	US Department of Commerce
US DOD	US Department of Defense
US DOE	US Department of Energy
US DOI	US Department of the Interior
US DOT	US Department of Transportation
USDA	US Department of Agriculture
VA	Veterans Administration

SOURCE(S): 1. Contracts and Grants
2. Guide for Initiating, Registering, Ordering and Billing for Research Studies - 1999