

## Best Practices for Creating and Updating Standard Operating Procedures (SOPs)

Welcoming remarks will begin at  
11:55 a.m. Eastern Time.

The formal presentation will begin at noon.

**For audio, dial in by phone:**

**+1-866-365-4406**

**Access code 5627649**

For a list of international toll-free numbers check your confirmation email for the direct link.

The following presentation reflects the personal views and thoughts of Patricia Reineke and Eulonda Whitmore and is not to be construed as representing in any way the corporate views or advice of University of Florida or Wayne State University nor the views or advice of the Association of University Technology Managers (AUTM). The content is solely for purposes of discussion and illustration, and is not to be considered legal advice.

# Best Practices for Creating and Updating Standard Operating Procedures (SOPs)

*Presented by:*

Patricia Reineke, University of Florida  
Eulonda Whitmore, Wayne State University

# Questions?

We will be taking questions during a designated question and answer period at the conclusion of the presentation. Please hold all questions until this designated period.

## Operator Assistance

Audio difficulties: Dial 0 0

Other issues: +1-847-559-0846

**Remember  
to complete your survey  
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**Thank You!**



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- AUTM Licensing Activity Survey (currently for United States and Canada)
- AUTM Update

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## Member Benefits

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**Patricia Reineke**  
Contracts Administrator  
University of Florida



**Eulonda Whitmore, CIA**  
Audit Quality Assurance Manager  
Wayne State University

**Best Practices for Creating or Updating Standard Operating  
Procedures (SOPs)**

**Patricia Reineke, University of Florida  
Office of Technology Licensing  
Eulonda Whitmore, Wayne State University  
Internal Auditor's Office**



- Create New Policies or Improve the Quality of Your Current Policies and Procedures
- Easily Update, Review, Approve, and Publish Documents
- Hold Employees Accountable for Comprehension of Policies and Procedures

### **Lack of Standard Operating Procedures**

- Causes employees frustration
- Non-productive



- Invaluable for new employee hires
- Ensuring all staff are using standard templates
- **Simplifies Compliance Efforts** - No more "hoping" you can show evidence of compliance. Quickly prove it!
- **Improves Overall Performance**  
With up to date documents distributed to the appropriate personnel, and tracking comprehension, performance will improve.
- **A tremendous tool** if you plan to install a new database!

- Don't document something your office isn't actually going to do...internal audit pitfall



- Create an Outline
- One section at a time

A.	Invention Disclosures
B.	Biological Material Invention Disclosures
C.	Creator Income Distribution Agreement
D.	Compliance-Government and Other S...
E.	Processing Patents
F.	Marketing
G.	Confidential Disclosure Agreements
H.	Material Transfer Agreements
I.	License Agreements
K.	Terminated Agreements
L.	Making Cases Inactive
M.	Off Site Storage Record Retention an...
N.	General Administrative Filing
O.	Inter- Institutional and Collaboration ...
P.	Interaction with UFRF DSR and OER
Q.	General Administrative Duties
R.	Negotiating IP Terms in Sponsored Re...
S.	Copyrights, Trademarks, Distance Lear...
T.	Miscellaneous Items Table of Contents
U.	Commercialization Fund
V.	UF Tech Connect
W.	Export Control
X.	Guidelines for Annual Portfolio Reviews
Y.	Surveys

- Invention disclosures
- Compliance
- Processing Patents
- Marketing
- General Admin/Misc
- License Agreements
- IIAs
- MTAs/CDAs
- Terminating Agreements
- Making cases inactive
- Export control
- Surveys, Requests for Data (Internal, AUTM, State)

- Letter(s) to inventor after receiving new disclosure
- Request for prior art search
- Decision letters from institution
- Report completed after meeting with inventor

- [A.01 Invention Disclosure Form](#)
- [A.02 Request for ODM](#)
- [A.03 Request to LO for Taxonomy](#)
- [A.04 Request For Prior Art Search](#)
- [A.05 Prior Art Search Letter to Inventor](#)
- [A.06 Letter to Inventor Regarding New Disclosure](#)
- [A.07 Oral Disclosure Report](#)
- [A.08 Waiver Letter](#)
- [A.09 Waiver Letter with Government Sponsor](#)
- [A.10 Exert Letter](#)
- [A.11 Premature Letter](#)
- [A.12 Waiver Request Checklist](#)
- [A.13 KSS Technology Manager Screen](#)

2.5		<ul style="list-style-type: none"> <li>• Prepare receipt letter to inventor(s). (See Exhibit <b>A.06</b>). Copy and paste into blank email, attaching the new Invention Disclosure. Verify email addresses of all UF inventors. Remove any non-UF inventors. Send email to lead inventor, copy all UF co-inventors, and send using "Sent on behalf of [Insert LO]" into the subject line of letter. Close report in KSS</li> </ul>	Team Secretary
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- Steps to enter information into database
- Distribute copies of disclosure
- Procedure to schedule meeting with inventor(s)
- Complete report confirming meeting

- If research was funded, report invention disclosure to sponsor
- Docket future dates to elect title, report patent(s), and send confirmatory license

## Examples of Details for Government Reporting

- Disclose within sixty (60) days of receipt by OTL. Use appropriate cover letter (Exhibit D.06, Disclosure Report Letter to Federal Agency) for agencies not in iEdison.
- Go out to the Compliance Manager on the main menu, highlight the "Edison Tech" and type in your case number in the blank box at the top to open the new Edison table that was created when you checked the Edison box.
- In the Edison table, enter Grant Agency and Grant No.
- If the Grant Number is not correct, you will get a message of improper formatting of grant number – you may need to log on to Edison at this point to obtain help with the proper formatting.

- Is technology jointly owned with another institution?
- Notify co-owner of invention disclosure
- Begin negotiations of Interinstitutional Agreement or Collaboration Agreement

 N. General Administrative Filing	:
 O. Inter- Institutional and Collaboration ...	:
 P. Interaction with UFRF DSR and OER	:

- Request prior art and marketing search
- Make decision on invention disclosure and send appropriate letter to inventor(s)
- If we exert, file patent application

- Send authorization letter to attorney
- Attorney works with inventor(s) to complete application
- Proceed to market the technology

•

E1.		Patent Application	
1.1		Forward patent application authorization to attorney, cc inventor and email into the patent record <a href="#">Exhibit E.01</a> .	Licensing Associate
1.2		<b>COMBINING CASES:</b> <ul style="list-style-type: none"> <li>Determine if any other cases are being combined with this patent application.</li> </ul>	
1.6		Upon receipt of patent application, verify the following: <ul style="list-style-type: none"> <li>Correct inventors are listed</li> <li>Assignees are correct</li> <li>Patent Application title is correct</li> <li>Government clause is included (if applicable)</li> </ul>	Licensing Associate

- Request marketing campaign; or
- Follow up on leads from inventor(s); or
- Direct contact with companies
- Notate method of marketing in database



●

F1.		Decision to Market	
	1.1	<p>When the filing status for a provisional patent application is changed to pending the Licensing Officer (CM) needs to make a decision about how they will be marketing this technology.</p> <p>If Licensing teams decide to request a targeted marketing campaign, they do so by completing the campaign request (<a href="#">Exhibit F.01, Sample Marketing Campaign Request</a>) then email request and provide any of the following resources that are available:</p> <ul style="list-style-type: none"> <li>• <i>Invention disclosure</i></li> <li>• <i>Patent application</i></li> <li>• <i>Relevant publications</i></li> <li>• <i>Prior art search report</i></li> <li>• <i>Related photos/graphics</i></li> </ul>	Licensing Team

●

F.4		<p><b>Removing TOS from Web</b></p> <p>When you receive an auto-generated email that a technology has been Exclusively Licensed, Optioned, or Inactivated, also if requested by Licensing Team, check to see if it is posted to the web. If so, do the following:</p>	Marketing Associate
F.5		<b>Press Releases</b>	
F.7		<p><b>Gathering New Contacts and Adding to Database</b> (from attendance at conferences; face-to-face meetings, etc.)</p>	

- Start with appropriate license template, i.e., exclusive; exclusive with know-how; non-exclusive; software; biological material; option, etc.
- Instructions for redlining

- 

II.		<b>NEGOTIATE TERMS OF THE AGREEMENT WITH POTENTIAL LICENSEE(S)</b>	Licensing Officer
		<ul style="list-style-type: none"> <li>• Legal Expenses: Request a quote for legal expenses from Contracts Administrator. Contracts Administrator should first check for related cases under the Classifications tab to ensure all legal expenses are included. Include all combined cases.</li> </ul>	Contracts Administrator
I4.		<b>PROCESSING EXECUTED OPTION OR LICENSE AGREEMENT</b>	

- Instructions for entering terms of Agreement into database
  - Interaction with financial office or accounting
- P. Interaction with the University of Florida Research Foundation, Inc. Business Office; the Division of Sponsored Research; And With the Office of Engineering Research (OER)

- 

Instruction Guide for Entering Fully Executed Agreements  
February 21, 2011

Exhibit 1.24

**INSTRUCTION GUIDE**  
**ENTERING FULLY EXECUTED**  
**LICENSE/OPTION AGREEMENTS**

Open agreement record and update according to these instructions.

**General Tab**

\_\_\_ The Agreement Title should be the same as the Title of lead case.

\_\_\_ Check box if **Sublicensable**.

\_\_\_ Enter correct agreement **Type** (i.e., Exclusive, Non-Exclusive).

\_\_\_ Change **Status** from "Under Negotiation" to "Active" in database.

\_\_\_ Correct **Manager** should be listed.

\_\_\_ Enter **Effective date**.

\_\_\_ Enter **Execution date**.

\_\_\_ Enter **Expiration date** (either expiration date of agreement, if one listed, or last patent expiration date. If not known, leave blank.)

- Steps to terminate
- Follow up on delinquent fees and milestones

1.2		<p>If decision is made to terminate the license, send following:</p> <ul style="list-style-type: none"> <li>• <a href="#">Exhibit K.01</a>, Notice of Default</li> <li>• <a href="#">Exhibit K.02</a>, Notice of Termination</li> <li>• <a href="#">Exhibit K.03</a>, Notice to Attorney of Termination</li> </ul> <p>If request to terminate comes from the Licensee, see Section K.2</p> <p>If default is cured, and Director wishes to send a notice that the default has been cured, use Exhibit K.06 Notice That Default Has Been Cured</p>	Contracts Administrator
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**CHECKLIST FOR TERMINATING/EXPIRING  
A LICENSE/OPTION AGREEMENT IN KSS**

**General Tab**

- \_\_\_ Change Status from "Active" to "Terminated" or "Expired" (if an option).
- \_\_\_ Enter Termination date or expiration date.
- \_\_\_ Save and Stay

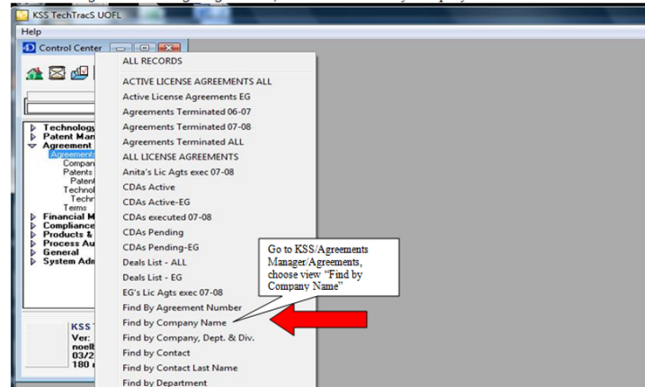
**IP Tab**

- \_\_\_ After clicking the IP Tab, click the "Relate to" button and choose Technologies. Then click the "relate to" button and choose agreements to see if the technology is licensed on another (non-terminated) agreement. For each technology that is no longer licensed change Technology Status to "Not Licensed". Close the Technology Window.
- \_\_\_ From the Agreement to IP tab: Update each Agreement Technology status from "Active" to "Terminated."
- \_\_\_ For each Agreement Technology record, update the "Transaction End Date" in the Period tables so that expenses will no longer be billed/deducted beyond that date. The Transaction End Date will be different per license.

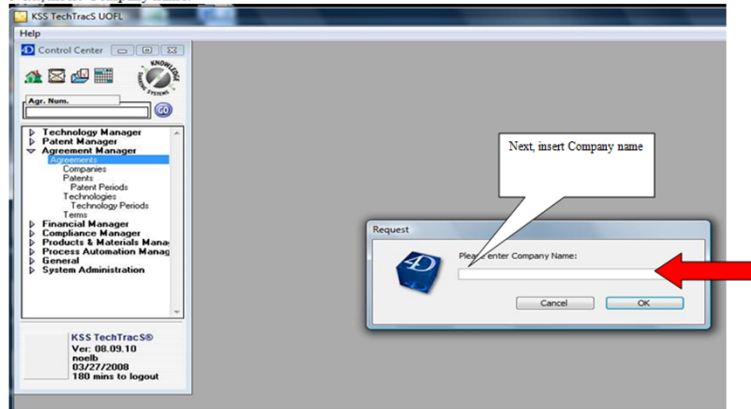
●	N1.	1.1	<b>Correspondence</b> <ul style="list-style-type: none"> <li>Copies of all correspondence (mailed, couriered, emailed and faxed) should be scanned and emailed in to the administrator in the database.</li> </ul>	Team Secretary
	N2.		<b>Documents for Files Already in Storage</b> Documents which need to be put in files already in storage should be scanned and emailed in to the case in the database.	Team Secretary
	N3.		<b>Creating Files</b>	Team Secretary
		d.	<b>How to update database when a company name changes.</b> See Exhibit N. 04 KSS Screen Shots for Changing Company Names	Licensing Associate

**HOW TO UPDATE KSS WHEN A COMPANY CHANGES NAMES-EXHIBIT N.04**

Go to KSS/Agreements Manager/Agreements, choose view "Find by Company Name"



Next, insert Company name.



- 

3.5	<p>License Agreement file          Once a license agreement is signed, create an electronic <u>Agreements_file</u> under inventor name. Under the Agreements folder, create the file below using the company name as part of file name</p> <ul style="list-style-type: none"> <li>• <u>LICENSEE AGREEMENT/AMENDMENTS ONLY</u>              The only documents in this file should be the original License Agreement and any Amendments</li> </ul>	Team Secretary
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## SOP: Can your DB create your Exhibits?

- [INSERT DATE]
- 
- [INSERT LEAD INVENTOR NAME]
- [INSERT ADDRESS]
- 
- Re: Invention Disclosure [INSERT UF# AND TITLE]
- 
- Dear [INSERT LEAD INVENTOR NAME]:
- 
- Thank you for your recent invention disclosure submission, received on [INSERT DATE]. We look forward to learning more about your discovery so we can collaborate with you in making an informed decision about the appropriate next steps regarding this technology.
- .....
- Sincerely,
- 
- [INSERT LICENSING OFFICER NAME]
- Assistant Director
- 
- cc: [INSERT UF CO-INVENTOR NAME(S)]
- [INSERT DEPT. CHAIRS NAME(S)]

## SOP: Can your DB create your Exhibits?

RE: Invention Disclosure UF#-14346 entitled "Monya Test Record"

Dear Dr. Dunlap:

Thank you for your recent invention disclosure submission, received on 08/09/12. Please review all information on the attached disclosure for accuracy, *specifically the inventor contact information, and contact us immediately if any changes need to be made.* We look forward to learning more about your discovery so we can collaborate with you in making an informed decision about the appropriate next steps regarding this technology.

If you haven't already heard from us, we will contact you soon to schedule a meeting to discuss your disclosure in detail. We will then conduct additional analysis as appropriate to determine both the patentability and commercial potential of your discovery. Based on this data, we will notify you in writing (within 120 days from disclosure) of the University of Florida's decision to either Waive or Exert its rights to your disclosure.

Sincerely,

Monya A. Dunlap  
Assistant Director

Technology=14346

Well written policies and procedures set the foundation and tone of effective internal controls over business processes. Management is responsible for developing and documenting policies and procedures. SOPs:

- Provide guidance and instruction
- Mitigate the risk of fraud
- Reduces operational inefficiencies and inconsistencies
- Encourages and motivates employees to do the right thing
- Holds employees accountable and responsible
- Facilitate training



*Remember that a procedure is the “how to” and the policy is the “requirement”*

Having outdated, incomplete or no SOPs increases the **risk** of:

- Inefficiencies
- Duplication of efforts
- Inconsistent practices
- Employees being unaware of required procedures
- Inability to enforce employee accountability
- Errors or inaccuracies
- An opportunity for fraud (*there is no policy that says I cannot do this*)



### Internal Audit's Perspective

Policies and procedures are only effective if people are aware of and understand them. Internal Audit will inquire of employees knowledge and awareness of SOPs. We also will inquire of the following:

- ✓ Are all significant business practices, processes, and policies and personnel responsibilities documented? (*the who, what, where, when and how*)
- ✓ Are policies and procedures written, reviewed and approved?
- ✓ Are University policies and procedures and federal/state regulations taken into consideration?
- ✓ Are policies and procedures available and communicated to all employees? If so, how? Are significant changes communicated to all employees?
- ✓ Are procedures periodically reviewed and monitored to reflect current practices, regulations and work towards continuous improvement and quality?
- ✓ Does management set an ethical tone to encourage compliance with procedures?
- ✓ Are exceptions to procedures documented, justified and approved?

### Internal Audit's Perspective

During an audit, Internal Audit will perform a risk assessment to identify the client's most significant business processes and :

- Gain an understanding of the internal controls, weaknesses, inefficiencies and risks by:
  - Inquiring of management and employees about the business process (i.e. process for license agreements or collection of milestone payments)
  - Reviewing the **established operating procedures manual**
  - Inquiring of employees about their knowledge of the operating procedures manual
  - Identifying internal controls, weaknesses, operational inefficiencies, and risks
- Perform audit procedures (test of controls and compliance)
- Provide recommendations for operational improvement

### Common Audit Issues related to SOPs:

- No standard operating procedures manual
- Missing important information such as a procedure, responsible party, etc. (i.e. process and responsible party for collecting milestone payments of monitoring agreements)
- No segregation of duties
- Duplication of efforts (two people performing same task)
- Inconsistent procedures and practices
- Outdated operating policies and procedures manual
- Policies and procedures not communicated to employees
- Operating procedures are not followed
- Employees are not trained on policies and procedures
- Operating procedures do not consider federal regulations (i.e. Bayh-Dole Act)



*SOPs are important!!*

- automated review, approval, distribution, and archival processes
- **Organizes Documents**  
Finally, no more lost or outdated policies!

### **Key benefits to purchasing software to track your SOPs:**

- Access Policies & Procedures Anytime, Anywhere, in Less Time
- Easily Review, Approve, and Publish Documents
- Hold Employees Accountable for Comprehension of Policies and Procedures
- Automate Versioning, Archiving, and Change History
- Quickly Access, Print, or Export Reports
- Categorize Documents Conveniently and Map them to Authoritative Sources
- Reduce the Time and Effort it Takes to Distribute Materials and Collect Attestations
- Improve the Quality of Your Policies and Procedures

- Outline
- One Section at a time
- It is a living document

- Don't be discouraged by the groans

- Keep pressing forward

- You will soon have a completed goal that makes you proud!

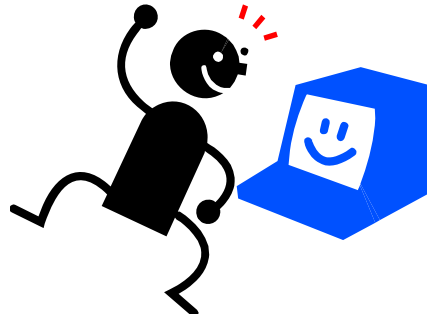


Business Office > Standard DOCS - SOP Manual >

Name	Date modified	Type
JOB DESCRIPTIONS & Back-Up Listing	9/20/2012 10:43 ...	File folder
Job Duties-CAROL	12/11/2012 2:44 ...	File folder
Job Duties-GEORGE	6/11/2008 2:23 PM	File folder
Job Duties-GREG	12/11/2012 3:01 ...	File folder
Job Duties-JACKIE	8/1/2012 3:59 PM	File folder
Job Duties-JULIE	1/26/2012 8:52 AM	File folder
Job Duties-MAUREEN	1/4/2013 3:09 PM	File folder
Job Duties-OPS	6/11/2008 2:22 PM	File folder
Job Duties-RACHEL	12/14/2012 3:00 ...	File folder
Job Duties-ROSALYN	12/11/2012 3:00 ...	File folder
Job Duties-TATYANA	10/8/2012 3:58 PM	File folder
SCANNING	7/25/2012 8:43 AM	File folder

- *How Do I Write a Standard Operations Procedures Manual?*
- *How to Write an Employee Operations Manual*
- *How to Get Employees to Write Detailed Procedures of Their Work*
- All of the above written by *Demand Media*

- <http://www.businessmanagementdaily.com/8770/get-organized-creating-sop-manual-is-easier-than-you-think>
- **Get organized! Creating SOP manual is easier than you think**





# Discussion and Q&A

**Click the raise hand button.**

When called on, press \* 7 on your telephone keypad to un-mute your phone.

Press \* 6 to re-mute your phone.



# Thank you for your participation.

Remember to complete  
our online survey.

## Webinar Recordings

Basics of Technology Transfer for Licensing Professionals  
Basic Patenting 101  
Copyright Law and Content/Software Licensing  
Equity Based License Agreements  
Financial Conflicts of Interest  
Marketing: Whether By Traditional or Social Media, the Value  
Need to Know Basics of Technology Transfer for Support Staff  
Negotiation of License Agreements  
Nuts and Bolts for Compliance Under Federal Funding Awards  
The Basics of Open Source Licensing  
Tips for Managing MTAs  
Triage  
Valuation of Inventions and Patents  
(More Added Monthly)

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box on Facebook and click "like"



Search groups for AUTM at  
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- **Export Control Basics for Administrative & Support Staff**
  - March 13
- **Introduction to Chinese Law & Patent Enforcement**
  - April 26
- **Technology Transfer and Social Media**
  - May 30
- **Managing Technology Transfer from a Small Office Perspective**
  - June 18
- **Contract Negotiations**
  - August 21
- **Many more to come!**

### AUTM Region Meetings

#### AUTM Central Region Meeting

July 17 – 19, 2013  
Hyatt Regency Indianapolis  
Indianapolis, IN USA

#### AUTM Eastern Region Meeting

Sept. 9 – 10, 2013  
The Boston Park Plaza & Towers  
Boston, MA USA

#### AUTM Western Region Meeting

Sept. 30 – Oct. 1  
The Nines Hotel  
Portland, OR USA



**Save the  
Date!**

AUTM Courses

AUTM Annual Meeting Courses

**Wednesday, Feb. 27**

- AUTM Advanced TOOLS Course
- AUTM Startup Business Development Course

**Friday, March 1**

- AUTM Advanced Marketing Course **NEW**
- AUTM Valuation Course



Save the  
Date!

AUTM Courses

AUTM Essentials of Academic  
Technology Transfer Course

October 23 – 25  
InterContinental Dallas  
Dallas, TX USA

AUTM Technology Operations and Organization  
Licensing Skills (TOOLS) Course

October 23 – 25  
InterContinental Dallas  
Dallas, TX USA



Save the  
Date!



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# AUTM 2013 Annual Meeting

**February 27 – March 2, 2013**

Henry B. Gonzalez Convention Center &  
San Antonio Marriott Rivercenter/Riverwalk  
San Antonio, TX USA

[www.autm.net/2013](http://www.autm.net/2013)

