

Accessing the OCR SharePoint PI Protocol eLibrary



Catherine Jahrsdorfer, R.N., B.S.N.

Liz Klingelhofer

Office of Clinical Research

May 4 & 5, 2012

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Pre-Test

- Q. Where are we with the contract on my new study?
- Q. Did we get a copy of the WIRB approval to proceed letter yet?
- Q. Has the budget been finalized?
- Q. Is the RAN done so I can get the workflow processed?
- Q. Has the sponsor paid us yet?
- Q. Does the IRB approved consent form language allow subject stipends to be paid using ClinCards?
- Q. Have we enrolled any participants in the study?

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Talking Point:

Today's topic will help you answers these questions in the future – without having to send an email or pick up the telephone!

Learning Objectives

- Learn how to request access to your PIs study folders in OCR SharePoint PI Protocol eLibrary
- Explore the file structure within the eLibrary and differentiate documents based on their naming convention
- Employ helpful hints for SharePoint navigation
- Apply access to the OCR eLibrary in daily practice



Problem

- OCR works with multiple stakeholders across the clinical research enterprise at USF and beyond
- Historically, information has been maintained in hard copy form in DSR “red files” and OCR post-award “white files”
- “Red files” travelled between OCR, DSR, General Counsel, and RF and were not always readily accessible
- Using a share drive such as a “G” or an “S” presented an access dilemma to stakeholders on the other side of the Health firewall

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Talking Point:

And sites did not have direct access to what activities were occurring “behind the scenes”.

Solution



- In Spring 2011 the OCR adopted SharePoint for electronic document management & storage on a shared web-based platform
- SharePoint allows access to individuals based on permissions, not domains
- To increase transparency to the study teams, OCR will grant View Only access to the OCR PI Protocol eLibrary on SharePoint
- Access will be given to study coordinators, clinical research administrators, PIs and other interested study team members

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Talking Point:

Accessing the OCR SharePoint site will allow the study teams to “help themselves” to up to date information about their study’s status from the OCR side, i.e. contract status, budget, checks received, what has been invoiced, SSLs submitted, etc.

What you will not see is study activity from the Department/site side such as vendors paid, etc.

Where to Begin?

- Complete OCR SharePoint Access Request Form
- Send completed forms to OCR@health.usf.edu
- Study Team Members will receive an email invitation to join the OCR SharePoint site



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Talking Point:

SharePoint operates best using Internet Explorer as your browser window. SharePoint may not have full functionality when using Firefox, Goggle Chrome or Safari.

SharePoint Access Request Form

**Access Given
to
SharePoint:
*View Only***

University of South Florida
Office of Clinical Research
Sharepoint Access Request Form

Principal Investigator (PI): _____ Date: _____

Study Team Members:	Member's Email:
1) _____	_____
2) _____	_____
3) _____	_____
4) _____	_____
5) _____	_____
6) _____	_____
7) _____	_____

By signing this form, the Principal Investigator or Accountable Office is requesting access to the Office of Clinical Research Sharepoint sites for their study team members and/or administrative staff. Users will be given *view only* access which allows documents within the named PI's study folder to be viewed. Please inform the OCR staff if a member of the study team no longer needs access. Please continue to send all study documents to OCR@health.usf.edu.

Documents within the Office of Clinical Research Sharepoint sites are covered by the Confidentiality Agreement.

PI / Accountable Officer Signature: _____ Date: _____

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Talking Point:


View Only access means members of this group can view pages, list items and documents. These permissions do not allow the members to add, edit, create or delete.

Study teams will be granted access at the PI folder level. We do not plan to “lock down” per study.

NOTE: Include the PI and department administrator(s) on the list of study team members who will need access!

Welcome to SharePoint!

WELCOME




Welcome to the SharePoint group: Clinical Research Owners for site: Office of Clinical Research

sharepointadmin
Sent: Wed 11/23/2011 9:10 AM
To: Klingelhofer, Elizabeth


Welcome to the 'Clinical Research Owners' SharePoint group. Hauser, Kimberlea (HSCNET\khauser) has added you to the 'Clinical Research Owners' group for this SharePoint site.
Group description: Use this group to give people full control permissions to the SharePoint site: Clinical Research

As a member of this SharePoint group, you can:

- * Participate in the SharePoint site at:
<https://my.usfhealth.usf.edu/clinicalresearch>
- * View the group home page at:
https://my.usfhealth.usf.edu/clinicalresearch/_layouts/people.aspx?MembershipGroupId=4224

Link to OCR Site 

NOTE: All information within the OCR SharePoint site is protected by the Confidentiality Disclosure Agreement for the study

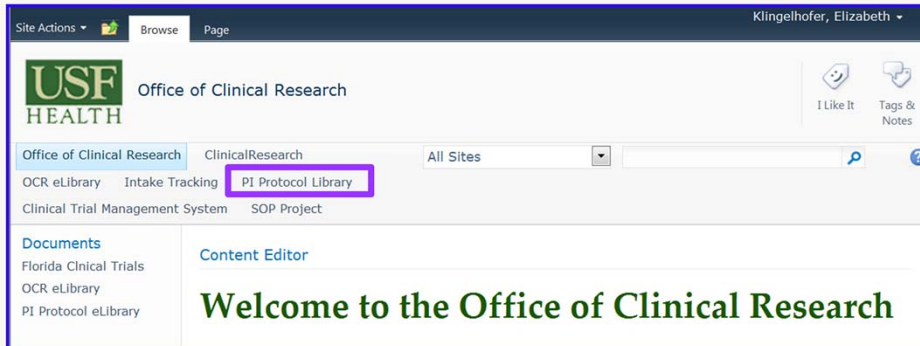
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Talking Point:

You will receive an email like this when access has been granted.

OCR SharePoint Homepage

- Select the PI Protocol Library
- ✓ List of all PI's



<https://my.usfhealth.usf.edu/clinicalresearch/default.aspx>

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Talking Point:

Main page of the OCR SharePoint site "Clinical Research".

There are multiple tabs within our site that you will not be able to access such as the CTMS site and the SOP site (for now).

Within the PI Protocol Library

Type	Name	Modified	Modified By	Checked Out To
Folder	Allen_Dwayne	4/24/2012 12:43 PM	Klingelhofer, Elizabeth	
Folder	Alrabaa_Sally	3/2/2012 10:35 AM	Klingelhofer, Elizabeth	
Folder	Anderson_Bruce	3/2/2012 10:25 AM	Klingelhofer, Elizabeth	
Folder	Ashmeade_Terri	3/2/2012 3:20 PM	Klingelhofer, Elizabeth	
Folder	Bahner_Ingrid	4/10/2012 7:36 AM	Klingelhofer, Elizabeth	
Folder	Benbadis_Selim	3/2/2012 3:39 PM	Klingelhofer, Elizabeth	
Folder	Bengtson_Michael	3/2/2012 3:51 PM	Klingelhofer, Elizabeth	
Folder	Bourne_Carla	3/2/2012 4:20 PM	Klingelhofer, Elizabeth	
Folder	Carter_John	3/5/2012 5:11 PM	Klingelhofer, Elizabeth	
Folder	Casanas_Beata	3/5/2012 5:38 PM	Klingelhofer, Elizabeth	
Folder	Cox_Charles	3/5/2012 5:49 PM	Klingelhofer, Elizabeth	



Locate your affiliated PI's folder

Example: Allen_Dwayne

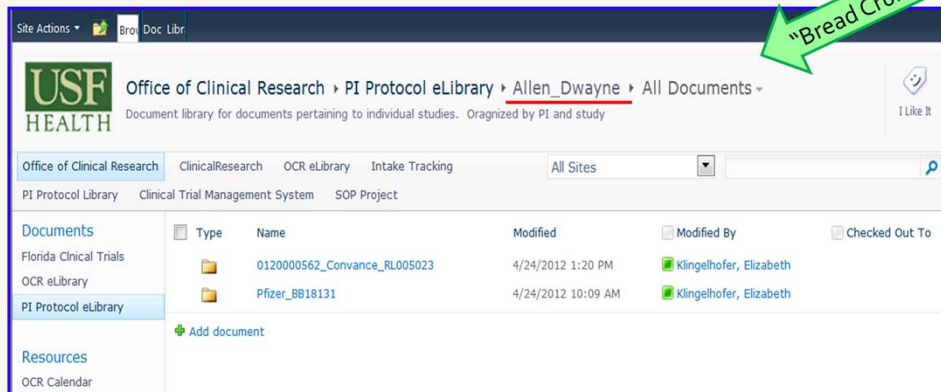
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Talking Point:

You will see a list of all your PIs with studies running through the OCR within the USF FAST system.

Study Folder Selection



The screenshot shows a web interface for the USF Health document library. At the top, there is a breadcrumb trail: "Office of Clinical Research > PI Protocol eLibrary > Allen_Dwayne > All Documents". A green arrow points to this trail with the text "Bread Crumbs". Below the breadcrumb trail, there are navigation tabs for "Office of Clinical Research", "ClinicalResearch", "OCR eLibrary", and "Intake Tracking". A search bar is visible on the right. The main content area displays a table of documents:

Type	Name	Modified	Modified By	Checked Out To
Folder	0120000562_Convance_RL005023	4/24/2012 1:20 PM	Klingelhofer, Elizabeth	
Folder	Pfizer_BB18131	4/24/2012 10:09 AM	Klingelhofer, Elizabeth	

Below the table, there is an "Add document" button and a "Resources" section with a link to "OCR Calendar".



Select the Study Folder of interest

Example: Pfizer_BB18131

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Talking Point:

Study folder naming convention = proposal #_sponsor_ protocol #

Study Folder Contents

Office of Clinical Research > PI Protocol eLibrary > ... Pfizer_BB18131 > Amendments

Type	Name	Modified	Modified By
Folder	Amendments	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
Folder	Regulatory Docs	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
Folder	Study Financial Management	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
Folder	Study Initiation	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
Document	OCR Form Header Template NEW	4/24/2012 1:20 PM	Klingelhofer, Elizabeth
Document	OCR_1 v2.0 New Study Questionnaire NEW	4/24/2012 1:20 PM	Klingelhofer, Elizabeth
Document	OCR_2 v2.0 Coverage Analysis Form NEW	4/24/2012 1:20 PM	Klingelhofer, Elizabeth
Document	OCR_4 v2.0 Internal Document Checklist NEW	4/24/2012 1:20 PM	Klingelhofer, Elizabeth
Document	OCR_5 v2.0 Communication Log NEW	4/24/2012 1:20 PM	Klingelhofer, Elizabeth



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Talking Point:

Main study folder will be set up in the same or similar fashion as this example.

Study Folder Contents

1. **Amendments** → Contract Amendments
2. **Regulatory Docs** → Protocol, ICF, IB, 1572, IRB application, etc.
3. **Study Financial Management** → Payments, Invoices, and Study Status Logs
4. **Study Initiation** → CTA, Budget, and LOI
 - **FINALs** → Mutually Agreed upon Budgets and Contracts between USF and Sponsor.



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Documents within main study folder:

- New Study Questionnaire
- Coverage Analysis Form
- Internal Document Checklist
- Communication Log



Talking Point:

Contents of these folders, including the documents on the main page of the folder, will evolve as the study progresses.

For a new study, blank forms are uploaded and the header information is inserted by OCR staff. Once documents are completed and returned to OCR, they are uploaded into the corresponding SharePoint folder. Naming conventions are updated accordingly.

Once the account has been opened, a copy of the RAN is uploaded into the main study folder as are copies of any modifications to the RAN.

Study Folder – Amendments

Site Actions | Bro | Doc Libr

USF HEALTH Office of Clinical Research > PI Protocol eLibrary > ... Amendments > All Documents

Document library for documents pertaining to individual studies. Organized by PI and study

Office of Clinical Research | ClinicalResearch | OCR eLibrary | Intake Tracking | All Sites

PI Protocol Library | Clinical Trial Management System | SOP Project

Type	Name	Modified	Modified By
	Amendment1_Allen_Pfizer_BB18131_(Sponsor-OCR)_4.20.12	4/30/2012 10:13 AM	Klingelhofer, Elizabeth

+ Add document

NOTE: Documents will have a different naming convention when uploaded by OCR into SharePoint

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Talking Point:

OCR renames documents when uploading into SharePoint in order to provide a common naming convention across all files and to provide names that are meaningful to OCR staff and our collaborators.

The Amendments folder is in reference to Contract Amendments – not protocol amendments or IRB amendments!

Study Folder – Regulatory Docs

The screenshot displays the USF Health Document Library interface. The breadcrumb trail at the top reads: Office of Clinical Research > PI Protocol eLibrary > ... Regulatory Docs > All Documents. A green arrow points to this trail with the text "Bread Crumbs". Below the breadcrumb trail, there are navigation tabs for "Office of Clinical Research", "ClinicalResearch", "OCR eLibrary", and "Intake Tracking". A dropdown menu shows "All Sites". Below this, there are links for "PI Protocol Library", "Clinical Trial Management System", and "SOP Project". The main content area is a table of documents:

Documents	Type	Name	Modified	Modified By
Florida Clinical Trials	Folder	IRB Approvals	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
OCR eLibrary	Document	ICFdraft_Allen_Pfizer_BB18131_4.24.12	4/24/2012 1:23 PM	Klingelhofer, Elizabeth
PI Protocol eLibrary	Document	Protocol_Allen_Pfizer_BB18131_4.24.12	4/24/2012 1:23 PM	Klingelhofer, Elizabeth

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Talking Point:

This is where prior IRB approval letters are archived, within the IRB Approval folder. We also upload a copy of the IRB approved consent to this folder. Any changes made to the consent that have a fiscal impact should also be forwarded to OCR@health.usf.edu, for example a change due to a revised payment method from USF check to ClinCard method.

The current version of the IRB approval letter will be located in the main study folder.

Study Folder – Study Financial Mgmt

Site Actions | Bro | Doc Lib

USF HEALTH Office of Clinical Research > PI Protocol eLibrary > ... Study Financial Management > All Documents >
Document library for documents pertaining to individual studies. Organized by PI and study

Office of Clinical Research | ClinicalResearch | OCR eLibrary | Intake Tracking | All Sites

PI Protocol Library | Clinical Trial Management System | SOP Project

Documents	Type	Name	Modified	Modified By
Florida Clinical Trials				
OCR eLibrary				
PI Protocol eLibrary	Folder	Sponsor Invoices	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
	Folder	Sponsor Payments	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
	Folder	Study Status Logs	4/24/2012 10:08 AM	Klingelhofer, Elizabeth

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Talking Point:

These are Sponsor invoices and payments, not those made to pay vendors, etc which is activity done at the Department level.

The GBR(s) will also be in this folder.

Naming convention appends the \$ amount of the payment or invoice to the title of the document.

Study Folder – Study Initiation

Office of Clinical Research > PI Protocol eLibrary > ... Study Initiation > All Documents -

Document library for documents pertaining to individual studies. Organized by PI and study

Office of Clinical Research ClinicalResearch OCR eLibrary Intake Tracking All Sites

PI Protocol Library Clinical Trial Management System SOP Project

Documents	Type	Name	Modified	Modified By
Florida Clinical Trials	Folder	FINAL Docs	4/24/2012 10:08 AM	Klingelhofer, Elizabeth
OCR eLibrary	Document	Budget_Allen_Pfizer_BB18131_4.24.12	4/24/2012 1:23 PM	Klingelhofer, Elizabeth
PI Protocol eLibrary	Document	CTA_Allen_Pfizer_BB18131_(Sponsor-OCR)_4.24.12	4/24/2012 1:23 PM	Klingelhofer, Elizabeth

Resources
OCR Calendar
Internal Form

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Talking Point:

Study initiation folder includes all versions of the contract during negotiation. Finals of the budget and contract are located in the FINALS folder.

Notice the dates appended to the name of the document – we are using these for tracking and reporting purposes.

Also note the “Modified” date and time to confirm the last time that a document was uploaded (but not necessarily modified as the name of the column may suggest).

Study Docs – New Study Questionnaire

- NSQ is completed with your Project Liaison
Amy Giordano or Susan Potter
- Naming convention will change to:
NSQcompleted_(PI)_(Sponsor)_(Protocol)_(date comp)



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Talking Point:

There are several documents that reside in the main study folder, including the new study questionnaire. The NSQ will be renamed after it is completed.

Revisions to the NSQ are imminent to ensure it addresses all of the critical information needed to get the study up and running expeditiously.

Study Docs – Document Checklist

USF OFFICE OF CLINICAL RESEARCH – INTERNAL DOCUMENT CHECKLIST			
Principal Investigator:	Allen, Dwayne	Study Coordinator:	Krystal Salgado
Department:	Pediatrics	Phone:	813-974-3336
Division:	Diabetes	E-Mail:	Ksalgado9@health.usf.edu
Phone:	813-974-3336		
E-Mail:	Dallen9@health.usf.edu		
Project Title:	Study Title HERE		
Protocol Number	DIABETES-35753		
Date Rec'd	Initials		
Drafts			
4/20/2020	EK	Clinical Trial Agreement (Grant Notice of Award) CTA reviewed by Patents & Licensing	
4/20/2020	EK	Budget	
4/20/2020	EK	Informed Consent Form	
		Protocol (Grant Proposal) **	
		OCR New Study Questionnaire (Form OCR-1) **	
IRB Related Documents			
		USF IRB WIRB Approval to Proceed Letter	
		Scientific Review Signature Page	
		IRB Application (Completed) **	
		IRB Approval Letter**	
		Informed Consent Form (IRB Approved)	

- Document Checklist – provides a list of all documents needed for each Clinical Trial



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Talking Point:

The Internal Document Checklist should look familiar to you as this is the same list that is sent out by OCR via email during the startup of a new study. As many of you know, the OCR now self retrieves as many of these documents as possible to reduce the burden on the study coordinator and to expedite the collection of essential documents.

Study Docs – Communication Log

USF OFFICE OF CLINICAL RESEARCH – COMMUNICATION LOG			
Principal Investigator:	Allen, Dwayne	Study Coordinator:	Krystal Salgado
Department:	Pediatrics	Phone:	813-974-3336
Division:	Diabetes	E-Mail:	Ksalgado9@health.usf.edu
Phone:	813-974-3336		
E-Mail:	Dallen9@health.usf.edu		
Project Title:	Study Title HERE		
Protocol Number	DIABETES-35753		
Project Liaison:	Amy Giordano or Susan Potter	USF Proposal/Project #	01201010252/ 61190999
Sponsor	Pfizer	Sponsor Contact	Norman Alan / Norman.Alan@Pfizer.com
CRO		CRO Contact	
Date	Communication	Initials	
4/20/2020	Rec'd CTA, Budget and ICF from Coordinator; uploaded to Sharepoint.	EK	
4/20/2020	Sent New Study Checklist to Krystal Salgado requesting additional docs.	EK	
4/21/2020	Sent CTA to P&L for review and edits.	rt	
4/21/2020	Rec'd P&L Edits on the CTA, uploaded to Sharepoint.	rt	
4/22/2020	Created Proposal Number in FAST.	EK	

- Communication Log – provides information documenting each step of the OCR process.




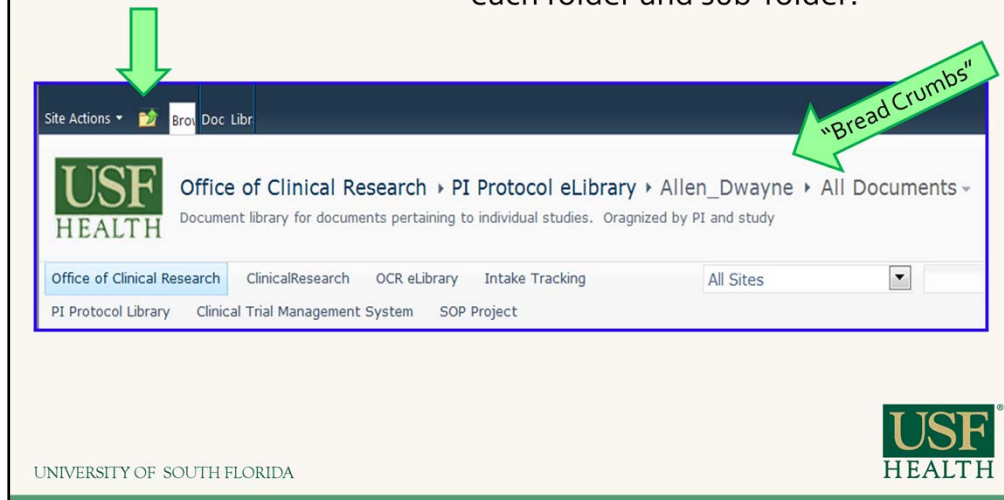
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Talking Point:

This is one of the best places to check to find out the status of a study....

Helpful Hints in SharePoint


- **“Bread Crumbs”** → indicates which folder you are viewing.
- **“Navigate Up”**  → allows user to navigate through each folder and sub-folder.

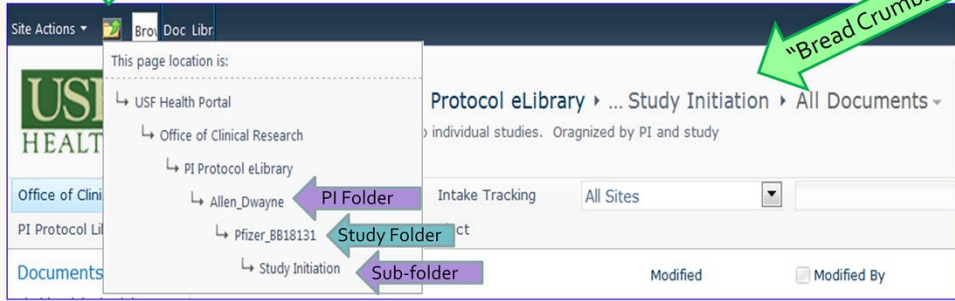


Talking Point:

The back button in the browser window can be a little sketchy and the breadcrumbs do not always work as designed in SharePoint 2010, so the Navigate Up button is your friend.

“Navigate Up” Features

- **“Navigate Up”**  → Provides a drop-down box with bread crumbs, which allows the user to navigate through each level of their PI’s Folder.



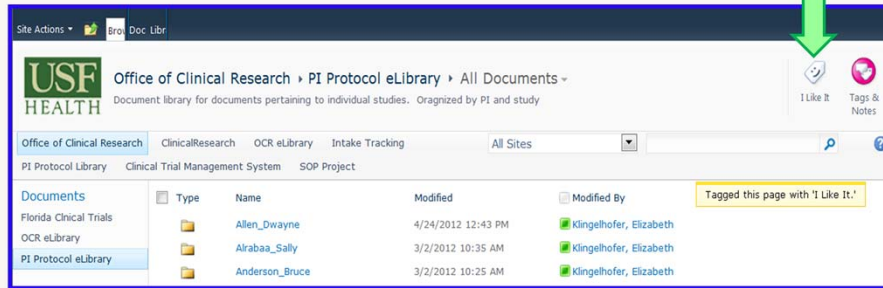
The screenshot displays the USF Health Portal interface. At the top, there is a navigation bar with 'Site Actions', 'Bro', and 'Doc Libr'. Below this, a 'This page location is:' section shows a breadcrumb trail: 'Protocol eLibrary > ... Study Initiation > All Documents'. A green arrow labeled 'Bread Crumbs' points to this trail. On the left, a tree view shows the folder structure: 'USF Health Portal' > 'Office of Clinical Research' > 'PI Protocol eLibrary' > 'Allen_Dwayne' > 'Pfizer_BB18131' > 'Study Initiation'. Three purple arrows point to these levels, labeled 'PI Folder', 'Study Folder', and 'Sub-folder' respectively. The USF Health logo and 'UNIVERSITY OF SOUTH FLORIDA' are visible at the bottom.

Talking Point:

If you use the “back” button on your browser window instead of the “navigate up” button, you may get an error message “Webpage has expired”. When this happens, click on the “refresh” button to bring you to the last page and cancel the error message.

Add OCR SharePoint to Your My Site

- Select the "I Like It" in the top left.
- Below will be your confirmation – OCR Site has been Tagged



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Talking Point:

My Site - Personal

The screenshot shows a SharePoint My Site profile for Elizabeth Klingelhofer. The profile includes a placeholder for a profile picture, a status box with the text "What's happening?", and contact information: "12901 Bruce B. Downs Blvd." and "eklinge1@health.usf.edu". Below the profile are navigation tabs: Overview, Organization, Content, Tags and Notes (selected), Colleagues, and Memberships. The main content area is titled "Tags and Notes" and shows a list of activities for May 2012. The activities include:

- Tagged Home - Office of Clinical... with which provides document m.... 5/2/2012
- Tagged Home - Office of Clinical... with This site has all PIs lis.... 5/2/2012
- Tagged PI Protocol eLibrary - Al... with I like it. 5/2/2012

Each activity has options for "View Related Activities", "Make Private", and "Delete". On the left side of the activity list, there are filters for "Refine by type" (All, Tags, Notes, Private, Public) and "Refine by tag" (Sort: Alphabetically, By Size). A note is visible: "I like it This site has all PIs listed by last name which provides document management within each study."

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Talking Point:

SharePoint My Sites are commonly referred to as “Facebook for the enterprise” and are personal site collections providing each user with the ability to store private and public information such as documents, pictures, status updates, etc easily and efficiently.

Need Help??



- For questions concerning the OCR SharePoint PI Protocol eLibrary, contact us at OCR@health.usf.edu
- For further training or for additional application inquiries for Microsoft SharePoint, contact Health IS at Support@health.usf.edu

Post Test

- Q. Where are we with the contract on my new study?
- Q. Did we get a copy of the WIRB approval to proceed letter yet?
- Q. Has the budget been finalized?
- Q. Is the RAN done so I can get the workflow processed?
- Q. Has the sponsor paid us yet?
- Q. Does the IRB approved consent form language allow subject stipends to be paid using ClinCards?
- Q. Have we enrolled any participants in the study?

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Talking Point:

Q1 – Check out the Communication Log and the Study Initiation folder.

Q2 – Check out the Regulatory Docs folder or the Internal Document Checklist

Q3 – Check out the Communication Log and the Study Initiation folder – especially the FINALS folder!

Q4 – It will be located in the main folder for the study

Q5 – Look within the Study Financial Management folder in the Sponsor Payments folder

Q6 – The IRB approved consent form will be found in the Regulatory Docs folder

Q7 – Sneak a peek at the most recent version of the SSL which resides in the SSLs folder inside the Study Financial Management folder

Questions,
Concerns,
Comments?



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