

Kuali Research Administration IRB

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Cornell University

Session Agenda

- Coeus IRB History & Current State
- KRA IRB Development Process
- KRA IRB User Interface – Mock Screens
- Coeus & KRA – Continuing Collaboration

Kuali Research Administration IRB

Coeus IRB History & Current State

- Planning for Coeus IRB started in 2003
- First roll out was in 2005 for Administrative Support (Back Office Operations)
- Version 4.3 has an improved Lite interface to allow submission of protocols to the IRB (Scheduled release Spring 2008)

- Components of Coeus IRB
 1. Submission of protocols to the IRB Administrative Office
 2. Assignment of protocols to an IRB and specific reviewers
 3. Development of IRB Agenda
 4. Review of the protocols by IRB reviewers
 5. Creation of Memos of Concerns/Approval to Investigators
 6. Electronic creation of minutes

- Types of Submissions processed by the IRB
 - Exemption
 - Expedited
 - New Protocol (Full Committee)
 - Continuations
 - Amendments
 - Closure
 - NOTE: Processing Unexpected Event/Adverse Event is a separate module that will be developed in the future

- Coeus IRB is overseen by the Compliance Subcommittee
- Other responsibilities include
 - Financial Conflict of Interest (upgrade as part 4.3.1)
 - IACUC (to be developed)
 - IBC (to be developed)
 - IRB Adverse Events (to be developed)

Kuali Research Administration IRB

KRA IRB Development Process

- Coeus is the product leader for Electronic Research Administration
- KRA started July 1, 2007
- KRA licensed Coeus software as the basis for all future KRA software
- KRA and Coeus working together on the development of new compliance modules (IACUC, Unexpected Events)
- KRA scheduled to replace Coeus Lite as the user interface for all Coeus applications
- There is the hopes that KRA and Coeus will eventually become one product

- Maintain all functionality from the Coeus product
- Apply development infrastructure & user interface consistent with Kuali
- Identify critical enhancements for consideration in Kuali product

- KRA IRB will be part of Release 2
- Functional specs and mock screens are in progress
- Code development will commence around June 2008
- First version of KRA IRB anticipated to be released by August 2009

Process: Module Development Steps

1. Subject Matter Experts (SMEs) review current product (Coeus) functionality
2. SMEs write specification documents
 - a. Enhancements to FC for review/vote
 - b. FC keeps tabs on scope throughout
3. Usability group build screen mockups
4. SMEs review screen mockups
5. Developers build code
6. Testers do quality assurance and report issues

Kuali Research Administration IRB

The User Interface
Mock Screens


Navigation Elements

IRB - Protocol 

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Protocol Type:	Version: 1

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Document Overview

* **Description:**

Explanation:


Org. Doc. #:

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Status & Dates 

Additional Information 

Organization 

Funding Sources 

Participants 

Keywords 

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IRB - Protocol 










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Required Fields for Saving Document 	
*Protocol #:	12351253
*Protocol Type:	select 
*Lead Unit:	select 
*Project Title:	<input type="text"/>
*Principal Investigator:	Employee Search  Non-employee Search 
*Area of Research:	<input type="text"/>  
*Application Date:	<input type="text"/> 
*Organization Type:	select 

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Status & Dates ?			
Protocol Status:	In Progress	Expiration Date:	12/14/2008
Initial Approval Date:	12/14/2006	Last Approval Date:	03/14/2007

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Additional Information ?

FDA Application Id:

Billable:

Reference ID1:

Reference ID2:

Exemption #: ▼

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Organization

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Organization ?

	*Organization Id	Address	IRB Contact name	FWA Number	Actions
Add:	<input type="text"/>				add
1	Home Office <small>Home Office</small>	ADE Corporation Newton, MA 02166	Wargel Joe	11111	clear address delete

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Funding Sources

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Funding Sources ?				
	*Funding Type	*Funding ID	Funding Description	Actions
Add:	<input type="text" value="select"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="add"/>
1	<input type="text" value="Sponsor"/>	<input type="text" value="713476"/>	<input type="text" value="NIH"/>	<input type="button" value="delete"/>
2	<input type="text" value="Other"/>	<input type="text" value="345787"/>	<input type="text"/>	<input type="button" value="delete"/>

Participants ▶ show

Keywords ▶ show

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Participants

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Participants ?			
	*Description	Count	Actions
Add:	<input type="text" value="select"/> ▼	<input type="text"/>	add
1	<input type="text" value="children"/> ▼	<input type="text" value="52"/>	delete
2	<input type="text" value="prisoners"/> ▼	<input type="text" value="23"/>	delete

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Keywords

IRB - Protocol 

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

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Keywords 		
Add:	Description	Actions
	(select) 	
1	Diabtes 	<input type="checkbox"/>
2	Carbon 	<input type="checkbox"/>
3	Chlorine 	<input type="checkbox"/>
4	Heat 	<input type="checkbox"/>
5	Longwave 	<input type="checkbox"/>
6	Transmittance 	<input type="checkbox"/>

Personnel

IRB - Personnel 

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Add Personnel:

*Person:	Employee Search 	*Protocol Role:	Principle Investigator 
	Non-employee Search 		

[clear](#)
[add personnel](#)

- Godfrey, Alberta D Principal Investigator [▶ show](#)
- McAfee, Alan E Key Person [▶ show](#)
- Rodby, Steve Correspondent - Administrator [▶ show](#)
- Mays, Lyle Correspondent - CRC [▼ hide](#)

Mays, Lyle

Correspondent Role:	CRC 	update view
Full Name:	Mays, Lyle	User Name: ha12189
Email Address:	hrclark@ll.mit.edu	Office Phone: 9999999999
Primary Title:	LI - Assistant Staff	Directory Title: LI - Assistant Staff
Home Unit:		School: MIT

Custom Data

IRB - Custom Data 

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Budget asdf asdf asdf asdf asdf asdf asdf asdf... [▶ show](#)

Personnel Items for Review [▶ show](#)

Project Details [▼ hide](#)

Project Details

Full Group Name: Project Details

Reference #1:	<input type="text"/>
Reference #2:	<input type="text"/>
FDA Application ID:	<input type="text"/>
Export Controls:	<input type="text"/>
Inventions:	<input type="text"/>  

Questions

IRB - Questionnaire 

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General Questions asdf asdf asdf asdf... [▶ show](#)

Participant Questions [▶ show](#)

Participant Questions

Full Group Name: Participant Questions

	Question	* Answer	Date	Explanantion	Actions
1	Will your participant sample include University students? <small>Explanation required: if answer = yes, no</small>	<input type="radio"/> yes <input type="radio"/> no	<input type="text"/> 	<input type="text"/>	details 
2	Will participants be compensated for their time? <small>Explanation required: if answer = yes, no</small>	<input type="radio"/> yes <input type="radio"/> no	<input type="text"/> 	<input type="text"/>	details 
3	Do you plan to use email or the Internet to recruit your participants? <small>Explanation required: if answer = yes, no</small>	<input type="radio"/> yes <input type="radio"/> no	<input type="text"/> 	<input type="text"/>	details 

Consent Questions [▶ show](#)

* required

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Special Review

IRB - Special Review 























































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Special Review

Special Review 

	*Type	*Approval Status	Protocol #	Application Date	Approval Date	Expiration Date	Exemption #	Comments	Actions
add:	<input type="text" value="select:"/> 	<input type="text" value=""/> 	<input type="text" value=""/>  	<input type="text" value=""/> 	<input type="text" value=""/> 	<input type="text" value=""/> 	<input type="text" value="select:"/> 	<div style="border: 1px solid #ccc; height: 40px;"></div> 	<input type="button" value="add"/>
1	Foundation Relations 	PENDING 	2723456  	12/14/05 	12/14/05 	12/14/06 	n/a 	<div style="border: 1px solid #ccc; height: 40px;"></div> 	<input type="button" value="delete"/>
2	International Program 	APPROVED 	4838685  	12/14/05 	12/14/05 	12/14/06 	E3 	<div style="border: 1px solid #ccc; height: 40px;"></div> 	<input type="button" value="delete"/>
3	Foundation Relations 	PENDING 	9345745  	12/14/05 	12/14/05 	12/14/06 	n/a 	<div style="border: 1px solid #ccc; height: 40px;"></div> 	<input type="button" value="delete"/>
4	International Program 	APPROVED 	2845345  	12/14/05 	12/14/05 	12/14/06 	n/a 	<div style="border: 1px solid #ccc; height: 40px;"></div> 	<input type="button" value="delete"/>
5	International Program 	PENDING 	3456622  	12/14/05 	12/14/05 	12/14/06 	n/a 	<div style="border: 1px solid #ccc; height: 40px;"></div> 	<input type="button" value="delete"/>

* required

Permissions

IRB - Permissions 

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Assigned Roles

Assigned Roles

Aggregator:	Smith, Davicia P
Viewer:	Cybil Cole, Bethany Davis, Cheryl Eger, Eric Swank
Role 3:	
Role 4:	

Users

Users

	*Person	User Name	Unit #	Unit Name	Role	Actions
Add:	<input type="text"/>				unassigned 	add
1	AOBECKFO	Beckford, Augustus O	165000	SB-SART	Aggregator	edit role clear roles delete
2	AAPHAM	Pham, Anibal A	165000	SB-SART	Viewer	edit role clear roles delete
3	davicia	Smith, Davicia P	165000	Center for Environmental Health Sciences	Viewer	edit role clear roles delete
4	iu_bd	Bethany Davis	999027	Indiana University	Viewer	edit role clear roles delete

* required

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Notes & Attachments

IRB - Notes & Attachments 


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Attachments (3) 

Attachments 

	Posted Timestamp	Uploaded By	*Attachment Type	Description	*File Name	Actions
Add:			select 	<input type="text"/>	<input type="text"/> <input type="button" value="Browse..."/>	<input type="button" value="add"/>
1	05/25/2007 10:44:18	HUNTLEY,KEISHA Y	attachment 1	my description...	myDoc1.doc	<input type="button" value="view"/> <input type="button" value="delete"/>
2	05/26/2007 10:44:18	HUNTLEY,KEISHA Y	attachment 2	my description...	myDoc2.doc	<input type="button" value="view"/> <input type="button" value="delete"/>
3	05/27/2007 10:44:18	HUNTLEY,KEISHA Y	Attachment 1	my description...	myDoc3.doc	<input type="button" value="view"/> <input type="button" value="delete"/>

Notes (2) 

Notes 

	Posted Timestamp	Author	*Note Topic	Note Text	Restricted?	Actions
Add:			<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="button" value="add"/>
				ma iustum et integrum? quo enim fugerunt, cum fugerent a facie tua? aut ubi tu non invenis eos? sed fugerunt, ut non		

Protocol Actions

IRB - Protocol Actions [?](#)

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Request an Action

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View Summary

[▶ show](#)

View History

[▶ show](#)

Print

[▶ show](#)

Ammendments & Renewals

[▶ show](#)

Copy to New Document

[▶ show](#)

Ad Hoc Recipients

[▶ show](#)

Route Log

[▶ show](#)

* required


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[route](#)

[close](#)

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Request and Action

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Request an Action

Request an Action

List of Actions

Submit for Review	<input type="checkbox"/>
Request to close	<input type="checkbox"/>
Request to close enrollment	<input type="checkbox"/>
Request to Re-open enrollment	<input type="checkbox"/>
Request for Data Analysis	<input type="checkbox"/>
Request for Submission	<input type="checkbox"/>
Request for Supervision	<input type="checkbox"/>
Withdraw Submission	<input type="checkbox"/>
Notify IRB	<input type="checkbox"/>
Terminate	<input type="checkbox"/>
Suspend	<input type="checkbox"/>
Submit Ammendment	<input type="checkbox"/>
Submit Renewal	<input type="checkbox"/>
Undo Last Change	<input type="checkbox"/>

Kuali Research Administration IRB

Coeus & KRA – Continuing Collaboration

- New development in Coeus IRB is ongoing with significant enhancements in recent releases
- Coeus consortium members participate in KRA SME group
- KRA SME members attend Coeus Compliance Committee meetings
- Two KRA partners currently implementing Coeus IRB

Keys to Success

- A solid Coeus IRB base to build on
- Structured Kuali process
- Involvement of functional experts (SMEs)
- A quality flexible product is critical to successful implementations
- Migration path for Coeus IRB users
- Good working relationship between Kuali and Coeus



Questions?