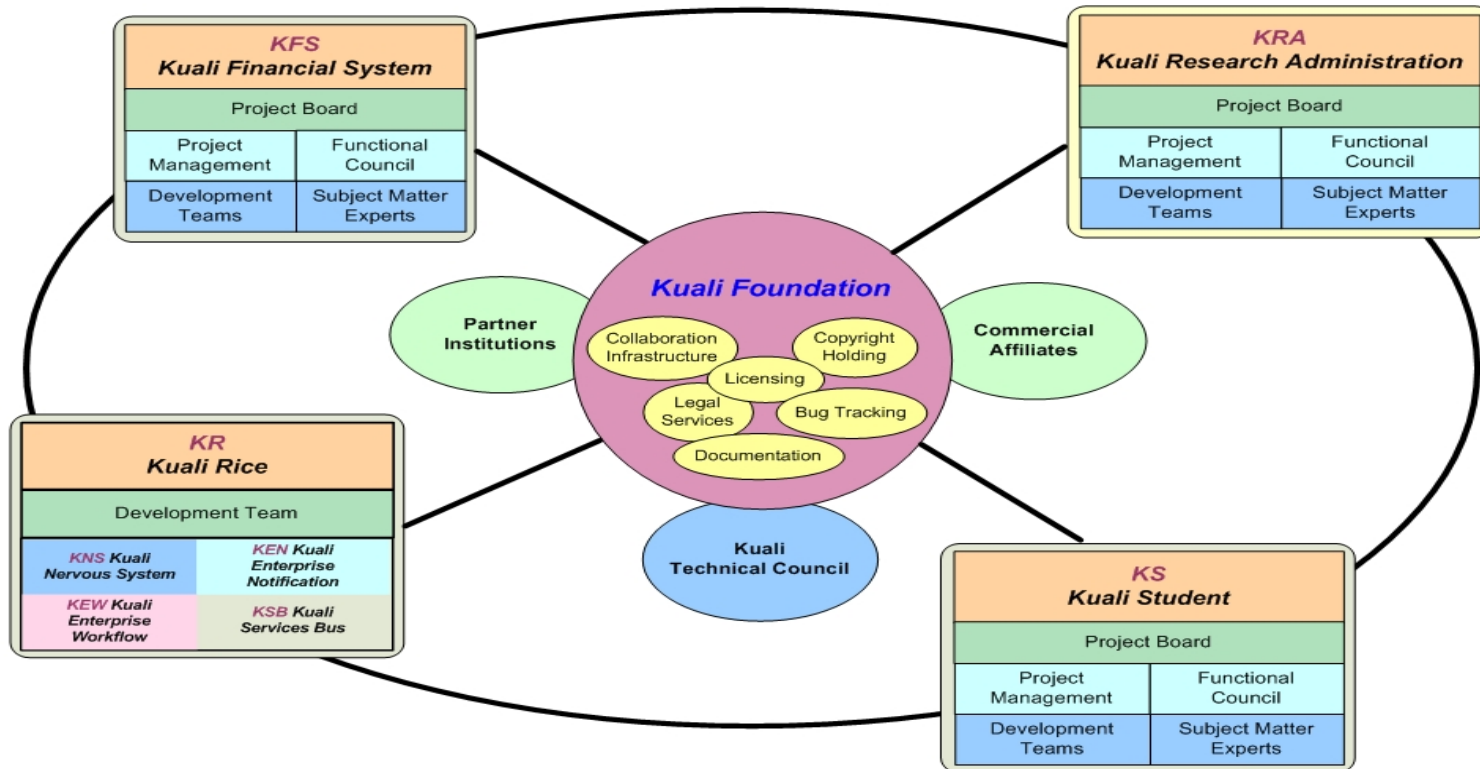# Kuali Research Administration Overview

KRA IRB SME Mirror Group

May 2007

Cornell University

What is Kuali & KRA

- Kuali began as a community/open source initiative to create a financial system for higher education.
- Kuali partners identified research administration gaps in financial modules
- Investigated best practices and licensed MIT Coeus
- Kuali Research Administration (KRA) launched
- Incorporates functions of:
  - Sponsored Program Solutions
  - Office of Research Integrity and Assurance

kuali

KRA - Partner Institutions

- Cornell University
- Massachusetts Institute of Technology
- Michigan State University
- University of Arizona
- University of Indiana
- Coeus Consortium institutions

kuali

Cornell University

Why Kuali at Cornell?

- Need for financial system upgrade lead to joining KFS effort

- Belief in community source model

- Recognition of gap in KFS functionality lead to support of and membership in KRA

- Interest in integration of financial, sponsored and research compliance systems

- Need for Grants.gov S2S and research compliance systems

kuali

Why Coeus at Cornell?

- Weill Cornell Medical College was already a Coeus user and consortium member

- Support for Kuali/Coeus collaboration – Ithaca campus joined Coeus Consortium at steering member level in May 2006

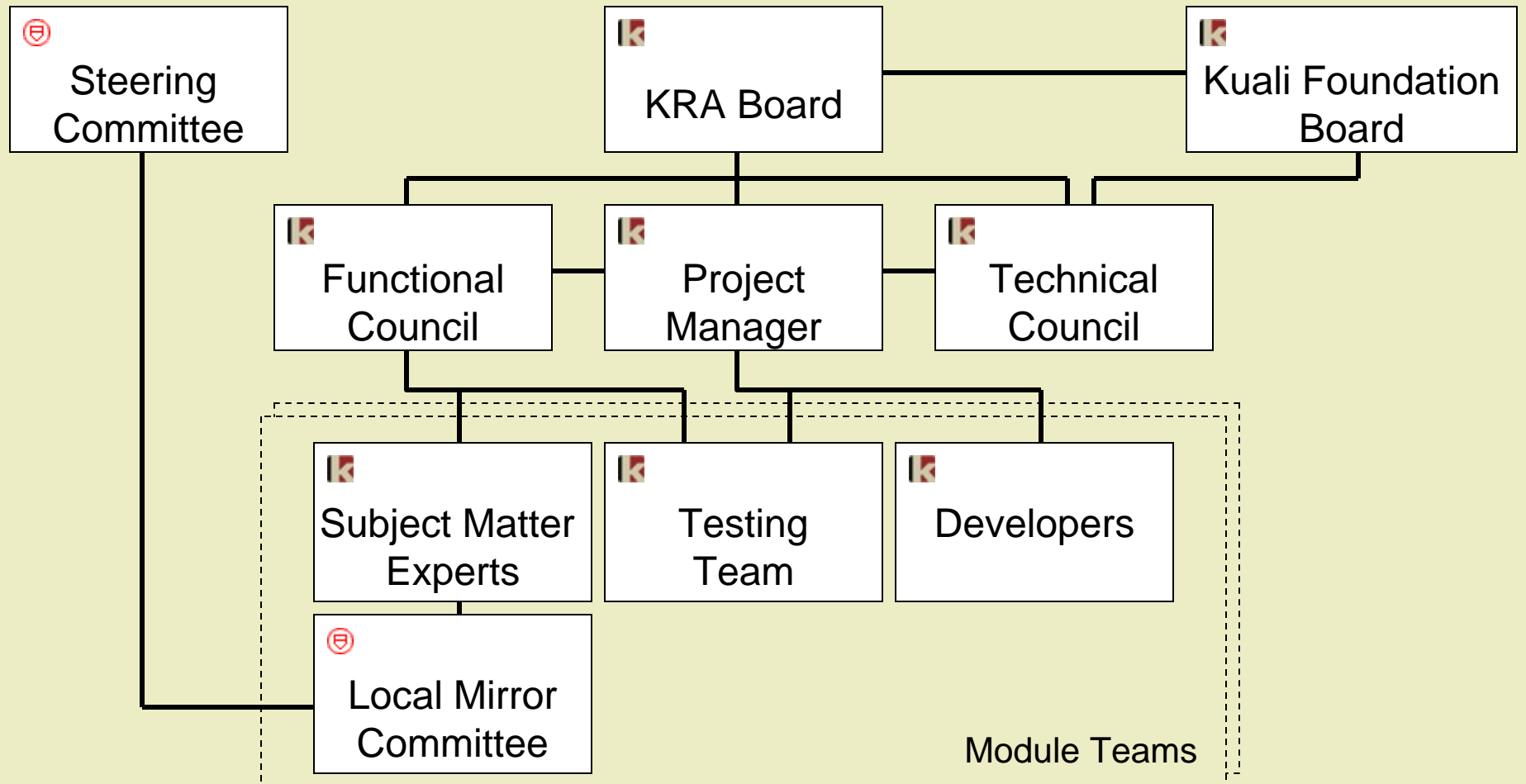- Ithaca campus plans to use Coeus IRB module interim solution to critical need while awaiting a KRA solution

kuali

KRA – Kuali Philosophy & Infrastructure

- Identify "best of breed" solutions from among partners as base for each module

- Common Kuali User Interface

- Leverage Kuali Rice architecture and development standards (nervous system, enterprise notification, enterprise workflow and service bus)

kuali

KRA – Governance Structure

- Report to the Kuali Foundation Board
- Share a Technical Council across all Kuali communities
- Separate KRA Board, Functional Council and Project Manager
- For each module create team of subject matter experts, developers and testers

kuali

Cornell University

Steering Committee

KRA Board

Kuali Foundation Board

Functional Council

Project Manager

Technical Council

Subject Matter Experts

Testing Team

Developers

Local Mirror Committee

Module Teams

kuali

Subject Matter Experts (SMEs)

- Group is formed with two to four members per partner institution. Participants part time

- Lead SME is identified. Works closely with development manager & business analyst

- Weekly conference calls and possible, but infrequent face-to-face meeting

- Translates functionality into specifications

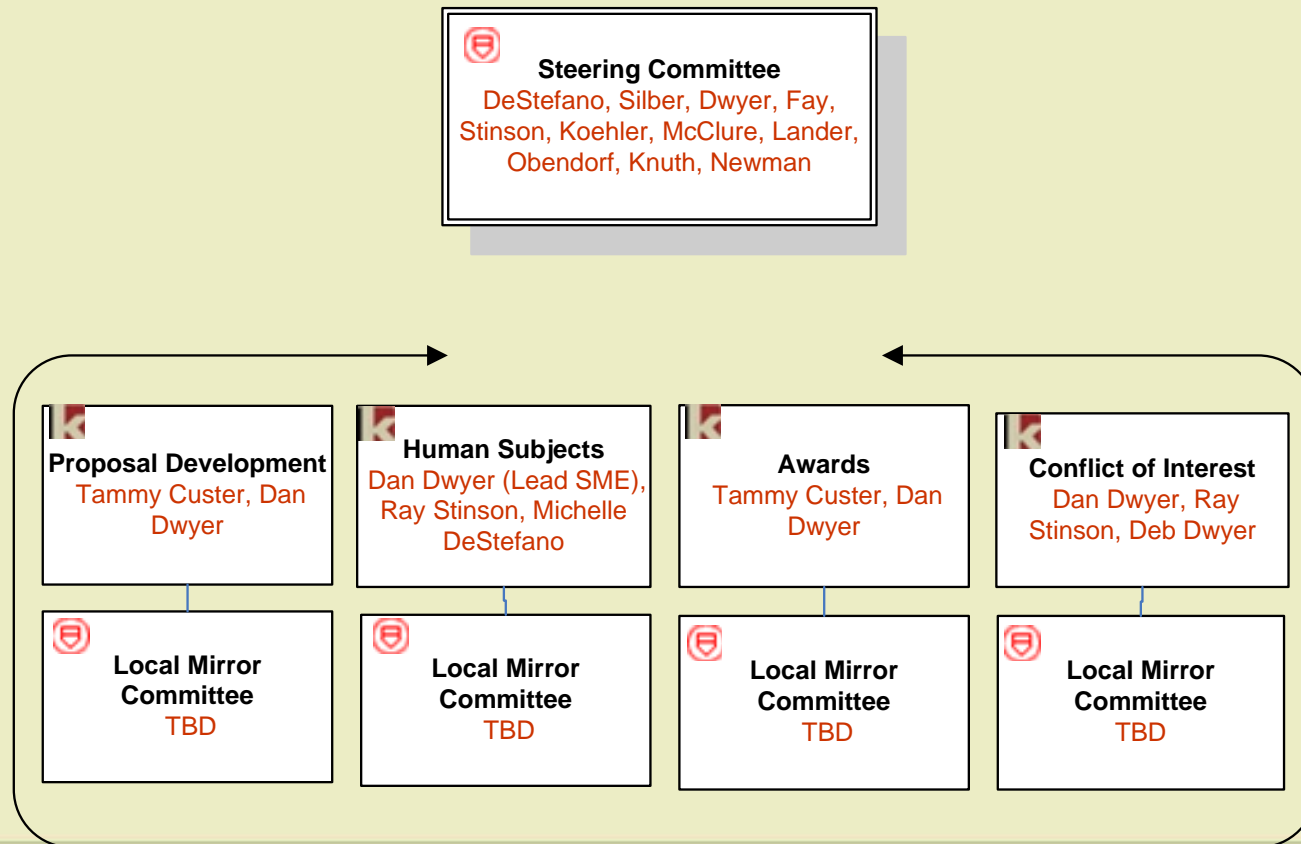- Validates code generated by developers.

Cornell SME Mirror Group

- Representative of all Cornell stakeholders for a specific KRA module

- Review KRA development and provide input on functionality and priorities to be fed back to KRA SME group

- Meet about monthly

- Respond via e-mail to specific questions as needed

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Cornell Organization (Functional)

Steering Committee
DeStefano, Silber, Dwyer, Fay,
Stinson, Koehler, McClure, Lander,
Obendorf, Knuth, Newman

Proposal Development
Tammy Custer, Dan
Dwyer

Human Subjects
Dan Dwyer (Lead SME),
Ray Stinson, Michelle
DeStefano

Awards
Tammy Custer, Dan
Dwyer

Conflict of Interest
Dan Dwyer, Ray
Stinson, Deb Dwyer

**Local Mirror
Committee**
TBD

**Local Mirror
Committee**
TBD

**Local Mirror
Committee**
TBD

**Local Mirror
Committee**
TBD

Coeus modules - Subject Matter Expert group currently active

kuali

First Priority Modules

- Proposal development (including budget template, routing & Grants.gov S2S)
- IRB
- Award
- Conflict of Interest

Second Priority Modules

- Proposal
- Negotiations
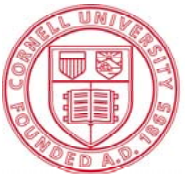- Report Tracking
- Subcontracts

kuali

Third Priority Modules

- Animal Use
- Export Control
- Institutional Biosafety
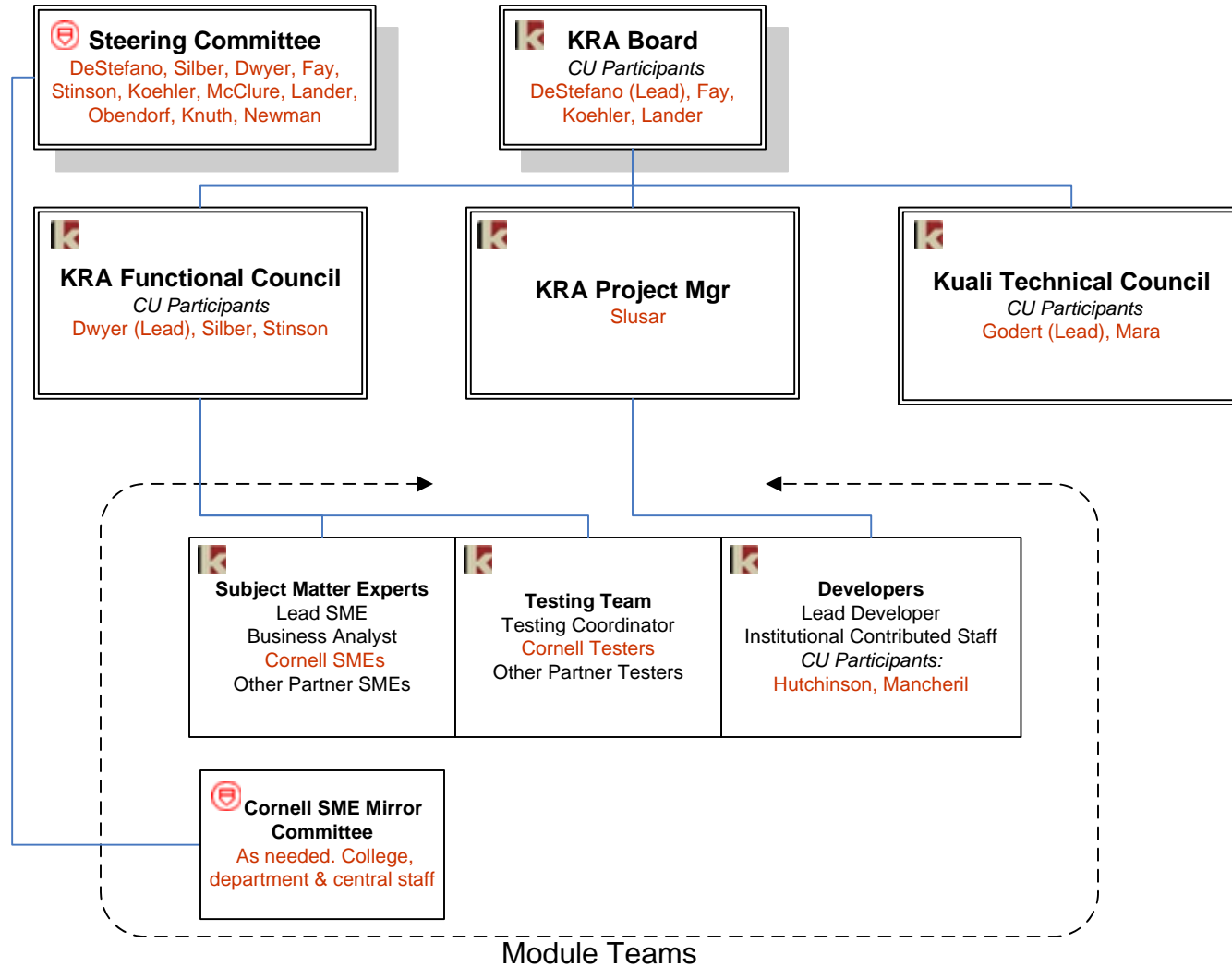- Chemical/Radiation safety

KRA – More Information

- Cornell Contacts
  - Joanne DeStefano, KRA Board member
  - Dan Dwyer, KRA Functional Council representative
  - Jeff Silber, Sponsored Programs
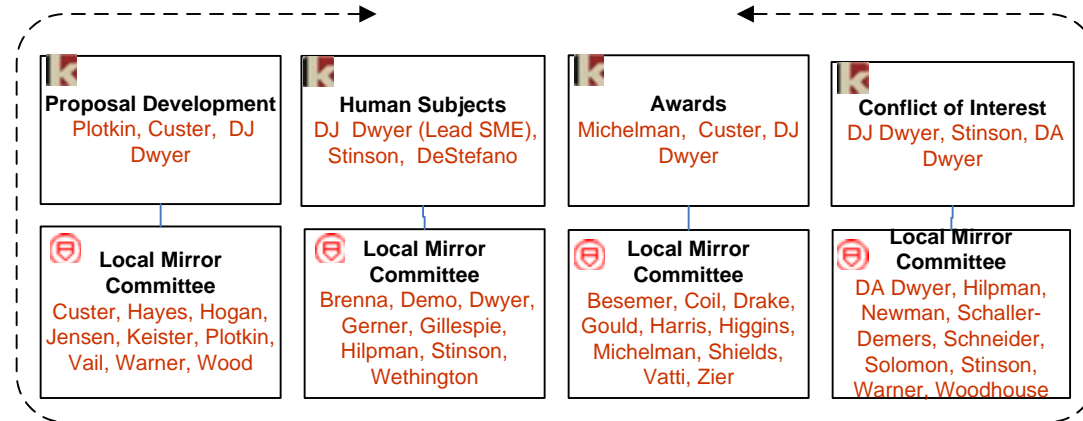 - Ray Stinson, Research Compliance
  - Bryan Hutchinson, KRA Developer
- http://www.kuali.org/communities/kra/

Cornell University

Kuali Research Administration
Cornell Organization Structure

kuali foundation

Steering Committee
DeStefano, Silber, Dwyer, Fay, Stinson, Koehler, McClure, Lander, Obendorf, Knuth, Newman

KRA Board
CU Participants
DeStefano (Lead), Fay, Koehler, Lander

KRA Functional Council
CU Participants
Dwyer (Lead), Silber, Stinson

KRA Project Mgr
Slusar

Kuali Technical Council
CU Participants
Godert (Lead), Mara

Subject Matter Experts
Lead SME
Business Analyst
Cornell SMEs
Other Partner SMEs

Testing Team
Testing Coordinator
Cornell Testers
Other Partner Testers

Developers
Lead Developer
Institutional Contributed Staff
CU Participants:
Hutchinson, Mancheril

Cornell SME Mirror Committee
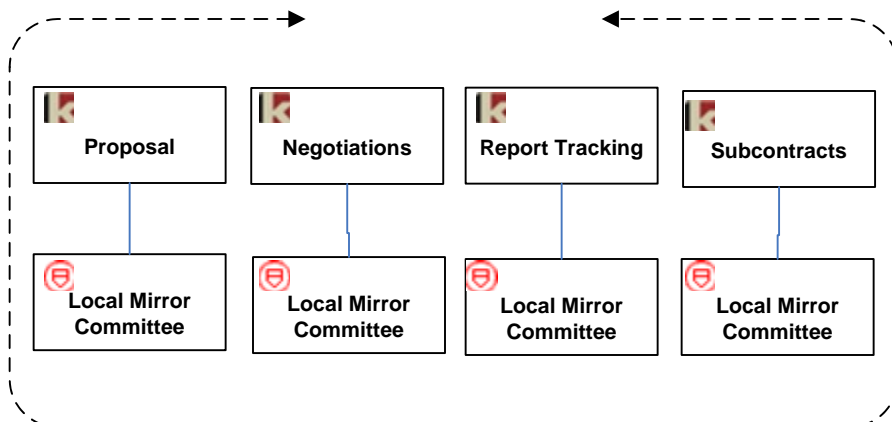As needed. College, department & central staff

Module Teams

Module teams will be formed as active development phases begin. Anticipated modules are proposal development (including budget development, routing and submission), proposal management, human subjects, compliance monitoring, award management, conflict of interest, award negotiation, report tracking, subcontracts, animal use, biological agents, radiation safety, export control and responsible conduct of research.
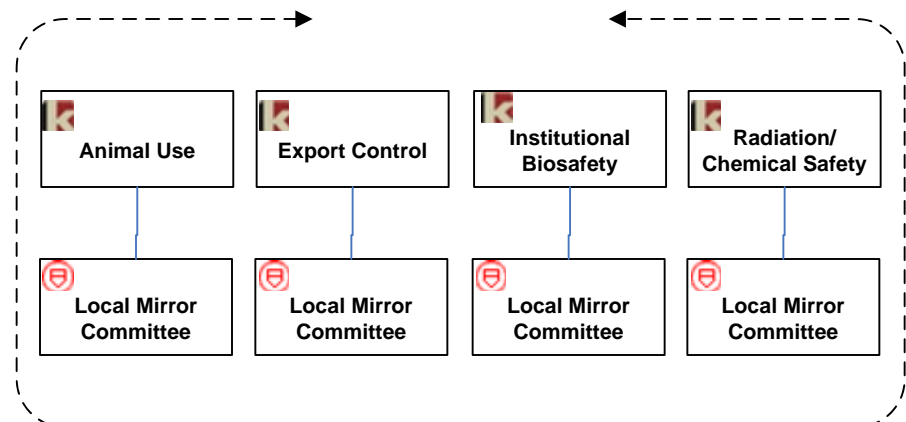
Kuali Research Administration
Cornell Organization Structure

Steering Committee
DeStefano, Silber, Dwyer, Fay, Stinson, Koehler, McClure, Lander, Obendorf, Knuth, Newman

Proposal Development
Plotkin, Custer, DJ Dwyer

Local Mirror Committee
Custer, Hayes, Hogan, Jensen, Keister, Plotkin, Vail, Warner, Wood

Human Subjects
DJ Dwyer (Lead SME), Stinson, DeStefano

Local Mirror Committee
Brenna, Demo, Dwyer, Gerner, Gillespie, Hilpman, Stinson, Wethington

Awards
Michelman, Custer, DJ Dwyer

Local Mirror Committee
Besemer, Coil, Drake, Gould, Harris, Higgins, Michelman, Shields, Vatti, Zier

Conflict of Interest
DJ Dwyer, Stinson, DA Dwyer

Local Mirror Committee
DA Dwyer, Hilpman, Newman, Schaller-Demers, Schneider, Solomon, Stinson, Warner, Woodhouse

Coeus modules - Subject Matter Expert group currently active

Proposal

Local Mirror Committee

Negotiations

Local Mirror Committee

Report Tracking

Local Mirror Committee

Subcontracts

Local Mirror Committee

Coeus modules – Subject Matter Expert group not yet active

Animal Use

Local Mirror Committee

Export Control

Local Mirror Committee

Institutional Biosafety

Local Mirror Committee

Radiation/ Chemical Safety

Local Mirror Committee

non-Coeus modules – Subject Matter Expert group not yet active

Revised 6/07

Kuali Research Administration Project

KRA-IRB
Committee Set-up

Functional Specification

Module - IRB

May 10, 2007

Table of Contents

Revision History

Version	Date	User	Description
1.0	5/10/07	Linda Triemer	Committee Setup
1.0	5/11/07	Dan Dwyer	Minor edits, added screen shot and error messages
1.1	5/16/07	Dan Dwyer	Reviewed with SME Group
1.2	5/16/07	Lora O'Connor	Update file name and title; Replaced Database Objects section with Field Definitions section; Added wording to Workflow and Permissions section; Adding wording to Additional Information
1.3	5/18/07	Dan Dwyer	Notes from 5/15 conference call incorporated

Functional Description

This function permits the set-up of a committee that is involved in the review and/or approval of a research protocol. The committee function, in general, allows a committee administrator to create the committee and identify members. The function should allow institutional flexibility to determine sufficient descriptor fields, e.g., member contact information, expertise, dates of appointment, etc. Initially the committee set-up capability will be used for IRB committees, but will be developed in anticipation that it will also be used for other committee types such as IACUC, IBC, limited submissions and internal review.

Business Requirements and Assumptions

[The Requirements and Assumptions section should always provide a list of the Business Requirements and a list of the Business Assumptions.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

Requirements

[The Business Requirements sub-section should list the top-level requirements of the module/document, i.e., the module/document should always do "XYZ".]

1. A specific administrator role is required to create or modify a committee
2. The committee must have an identifier, name and home unit

Assumptions

1. The Committee must have members prior to use
2. Committees will have scheduled meetings
3. Protocols will be assigned to scheduled meetings for review and approval

Business Rules

If a committee is named, the function requires at least one member (or administrator) to be named.

Unclassified

[The Unclassified Business Rules sub-section provides a listing of the rules that aren't initially associated with Universal, Universal with Institutional Values or Coeus/MIT Specific. These rules should be placed under the three main sub-sections as analysis progresses.]

None at this time

Universal

[The Universal Business Rules sub-section provides a listing of the rules that are standard across all KRA institutions as written.]

Universal with Institutional Values

[The Universal with Institutional Values Business Rules sub-section provides a listing of the rules which are standard across all KRA institutions but refer to institution-specific data values that may differ across institutions and may require additional/different value entries.]

It is recommended, but not required that the OHRP registration number is used as the value for Committee ID on each committee

Coeus/MIT Specific

[The Coeus/MIT Specific Business Rules sub-section provides a listing of the rules that are specific to Coeus/MIT and can either be adopted by other KRA institutions, replaced with similar institutional-specific rules, or simply commented out.]

None at this time

Batch Scheduling (optional)

[The Scheduling section provides a detailed review of the scheduling for a batch job. It should include jobs that should complete before this job, jobs that should run after this one and scheduling of this job.]

None at this time

System Integration Points (optional)

[The System Integration Points section provides a detailed description of requirements this function has for integrating with other non-KRA internal or external systems.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

Initially the committee set-up capability will be used for IRB committees, but will be developed in anticipation that it will also be used for other committee types such as IACUC, IBC, limited submissions and internal review.

Government Regulations

Business rules defined throughout this document are based on the following federal regulations

> 45 CFR 46.107 – Institutional Review Boards
>
> 45 CFR 164.512(i)(1)(B) – Privacy Boards
>
> 7USC, 2131-2156 Animal Welfare Act – Institutional Animal Committees
>
> 21 CFR 50.56 FDA Protection of Human Subjects
>
> Dept of Education Regulations for Disabled persons (need official name)

Flow of Events (optional)

The administrator sets up the committee with members, and the relevant contact information and descriptors. The system permits a printout of a roster that meets committee specific requirements, e.g., OHRP, AAHRPP

Main Success Scenario – Enter new committee

[A brief description of the Success Scenario is presented here.]

Actor/Role Actions	System Actions
1. Adminstrator selects Committee management link	
	2. System returns a list of current committees
3. Administrator selects "Add Committee" button	
	4. System displays committee eDoc with blank fields
5. Administrator enters committee information. Committee ID, Committee Name and Home Unit are required fields	
6. Adminstrator clicks "save" button	
	7. System stores committee record
8. Administrator clicks Close Committee button or closes window	
	9. System closes Committee Detail window

Alternate Flows – Modify committee

[The Alternate Flows sub-section provides additional flows beyond the main success scenario.]

Actor/Role Actions	System Actions
1. Adminstrator selects Committee management link	
	2. System returns a list of current committees
3. Administrator selects a committee from list	
	4. System displays committee eDoc with fields populated
5. Administrator enters committee information. Committee ID is not editable. Committee Name and Home Unit are	

required fields	

Alternate Flows – Close without saving

[The Alternate Flows sub-section provides additional flows beyond the main success scenario.]

Actor/Role Actions	System Actions
1. Administrator enters committee information. Committee ID, Committee Name and Home Unit are required fields	
	2. System displays message "Do you want to save changes" [Yes] [No] [Cancel]
3. Administrator selects [Yes]	
	4. System saves record and closes Committee detail window

Pre-Conditions

[The Pre-Conditions sub-section provides a listing of the conditions that must be true for the inputs to ensure a successful execution of an action. For example, a user wants to access the system. He must have a valid account.]

1. User wants to access Committee module

The committee administrator role has been defined to include the ability to setup a committee and committee roster

2. Unit table has been populated

The Committee panel of the Committee detail window requires that the system unit table is populated with the unit hierarchy which can be searched and units selected.

Post-Conditions

1. Committee exists and people with appropriate role can view and select it.

[The post-condition is presented here.]

Pages and Actions

[The Pages and Actions section provides a detailed review of the function that will be represented in the document. This section should include process descriptions, flowcharts, activity diagrams or other descriptions of functionality.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

Screen Shot

[The name of the function, screen and the actual image are presented here.]

Screen Shot 1: Coeus Committee Select Window
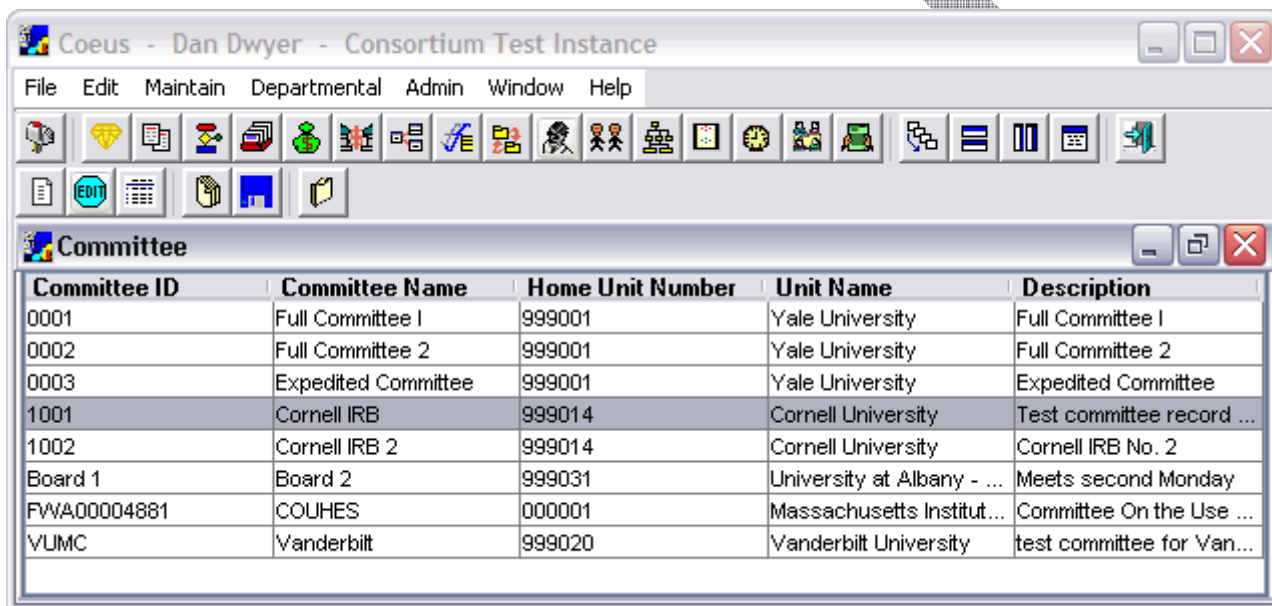
Actions / Responses

Action	Response
Double click on Committee row	A read-only view of the committee window is displayed
Highlight committee row and click edit button	An editable view of the committee window is displayed

Screen Shot 2: Community Detail Window, Committee Panel

Actions / Responses

Action	Response

Add Home Unit Screen shot and action/responses here

Screen Shot 3: Community Detail
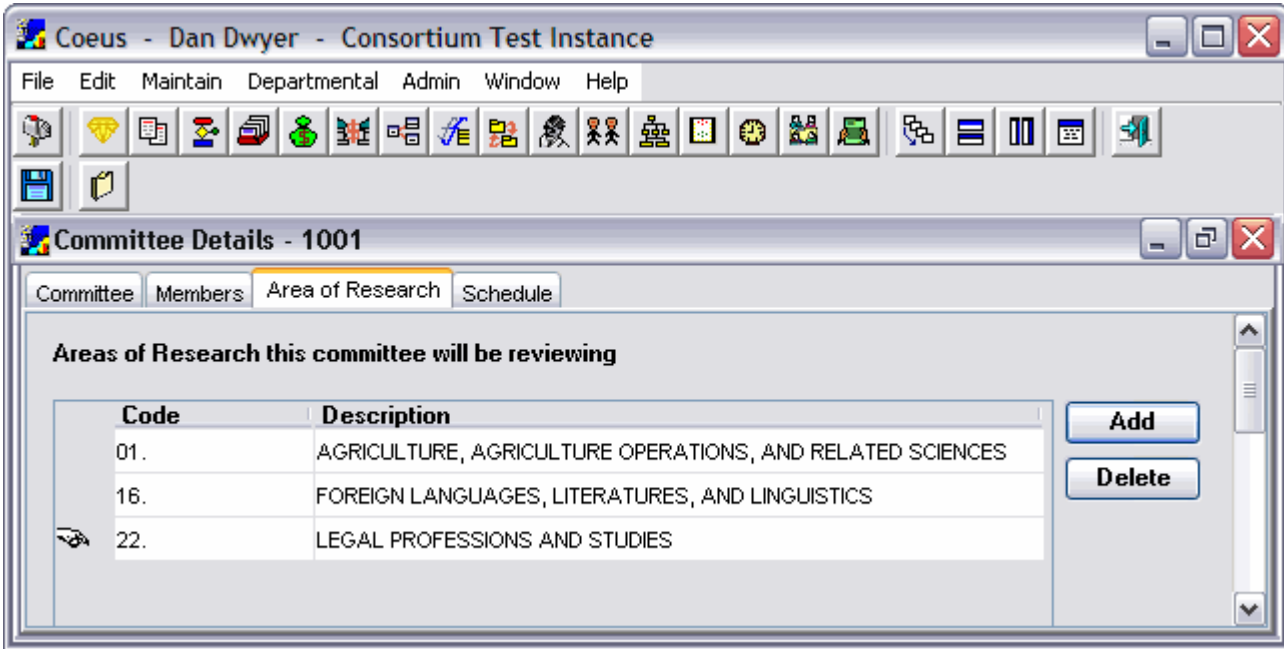
Actions / Responses

Action	Response
Click Add Button	*Area of research – Select Node window appears*
Select Area of Research and click delete button	Message appears "Are you sure you want to delete this area of research?" [Yes] [No]
Choose [Yes]	Area of research is removed from Area of Research panel
Choose [No]	Message window removed. Return to Area of Research panel

Area Of Research - Select Node

```
   000001 : All Research Areas
 +   01. : AGRICULTURE, AGRICULTURE OPERATIONS, AND RELATED SCIENCES
 +   03. : NATURAL RESOURCES AND CONSERVATION
 +   04. : ARCHITECTURE AND RELATED SERVICES
 +   05. : AREA, ETHNIC, CULTURAL, AND GENDER STUDIES
 +   09. : COMMUNICATION, JOURNALISM AND RELATED PROGRAMS
 +   10. : COMMUNICATIONS TECHNOLOGIESTECHNICIANS AND SUPPORT   SERVICES
 +   11. : COMPUTER AND INFORMATION SCIENCES AND SUPPORT SERVICES
 +   12. : PERSONAL AND CULINARY SERVICES
 +   13. : EDUCATION
 +   14. : ENGINEERING
 +   15. : ENGINEERING TECHNOLOGIESTECHNICIANS
 +   16. : FOREIGN LANGUAGES, LITERATURES, AND LINGUISTICS
 +   19. : FAMILY AND CONSUMER SCIENCESHUMAN SCIENCES
 +   21. : TECHNOLOGY EDUCATIONINDUSTRIAL ARTS
 +   22. : LEGAL PROFESSIONS AND STUDIES
 +   23. : ENGLISH LANGUAGE AND LITERATURELETTERS
 +   24. : LIBERAL ARTS AND SCIENCES, GENERAL STUDIES AND  HUMANITIES
 +   25. : LIBRARY SCIENCE
 +   26. : BIOLOGICAL AND BIOMEDICAL SCIENCES
 +   27. : MATHEMATICS AND STATISTICS
 +   28. : RESERVE OFFICER TRAINING CORPS (JROTC, ROTC)
 +   29. : MILITARY TECHNOLOGIES
 +   30. : MULTIINTERDISCIPLINARY STUDIES
 +   31. : PARKS, RECREATION, LEISURE AND FITNESS STUDIES
```

OK
Cancel
Search

Actions / Responses

Action	Response
Highlight Area of Research and click OK	*Area of Research is added to list on Area of Research Panel.*
Click Search Button	Area of Research Search Window is displayed
Click Cancel	Area of Research Select Node Window is closed. No other action taken.

Error Messages

[The Error Messages section should provide an overview of how messages will be handled for the function that will be represented in the document. Most of the functions will require error messages related to saving data to the database (ex: characters in a numeric field). However, there are some functions that require error messages that relate directly to business rules validation. It might be necessary to list error messages in this section or list error messages within the Business Rules section.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

1. Committee ID field required

Committee ID field cannot be blank, Please enter Committee ID.

2. Committee Name field required

Committee Name cannot be blank. Please enter a name.

3. Unit number field required

Unit number cannot be blank. Pease select a Unit number.

Workflow and Routing

[The Workflow and Routing section provides an overview of the workflow and routing actions and rules for the function represented in the document.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

No routing of committee setup or changes is required.

Workflow Actions (optional)

[The Workflow Actions sub-section provides an overview of workflow interactions.]

Routing Rules and Actions (optional)

[The Routing Rules and Actions sub-section provides an overview of routing. Routing rules indicate where a particular transaction is routed based on the validated data contained in the transaction.]

Document Statuses (optional)

[The Document Statuses sub-section provides an overview of the different status values that a document can have and when transitions between these statuses occur.]

More detailed information on Workflow and Routing will most likely be handled in a separate specification document.

Refer to the Additional Information section in this document for specific Confluence/Oncourse/Coeus URL references to Workflow and Routing (KEW) information.

Permissions

[The Permissions section provides an overview of the permission structure related to this function. This section should include roles, actions and states. It might be necessary to present the roles, actions and states in this section or within the Business Rules section.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

More detailed information on Permissions/Rights will most likely be handled in a separate specification document.

Refer to the Additional Information section in this document for specific Confluence/Oncourse/Coeus URL references Permissions/Rights information.

Additional Information (optional)

[The Additional Information section can be used to provide supplemental information for the function that will be represented in the document. It may be necessary to include supplemental information for clarity to readers (ex: definitions).

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

Definitions

[The Definitions sub-section should contain terms that help define the function.   They can be defined in any order desired, but generally alphabetical order provides the greatest accessibility.]

NOTE: All Definitions should be added to the main KRA Glossary.
https://test.kuali.org/confluence/display/KRACOEUS/KRA+Glossary

To be added to Glossary:

Committee
Member
IRB - **INSTITUTIONAL REVIEW BOARD (IRB):** 1. A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials in the U.S. must be approved by an IRB before they begin. 2. Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have an IRB that initially approves and periodically reviews the research in order to protect the rights of human participants. (source clinicaltrials.gov)

References

[This References sub-section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

Field Definitions

[The Field Definitions sections can be used to identify information about specific fields, including label name, title and description, length, required or not required.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

xxxx Tab

Data Label	Title and Description	Additional Information
Label Name for Field #1	***Label Name Full Title*** *Describe the field in more detail and what it is used for. Is this the description that should appear in any help information on the page?*	*xx characters -* ***Required***
Label Name for Field #2	***Label Name Full Title*** *Describe the field in more detail and what it is used for. Is this the description that should appear in any help information on the page?*	*xxx alpha/numeric –* ***Not Required***
Label Name for Field #3	***Label Name Full Title*** *Describe the field in more detail and what it is used for. Is this the description that should appear in any help information on the page?*	*xx numeric*

Questions/Issues

[The Questions/Issues section provides a list of items that are concerns to the Business Analyst, DM, Lead Developer or SME with regard to the function that will be represented in the document.

This section can include references. Specify the sources from which the references can be obtained. This information may be provided by reference to another document.]

1. Should Area of Research panel be merged with Committee Panel?

The area of research panel on the committee screen has only one field of data on it. It likely was separated from the committee panel to reduce screen size. Because Kuali is web based with scrolling and hidable sections, it seems logical to combine the Area of Research panel with the committee panel.

2. Is Committee Type a value that is universal with business rules associated with it or configurable by institution?

If there are business rules behind this value it may need to be universal value. Also as other committee types are added (IACUC, IBC, etc) values will need to be expanded.

3. Do we require or recommend use of OHRP registration number?

Or do we have a separate field for it.

4. Should additional fields be required fields?

e.g., At least one member, area of research?

5. Area of science values?

Should these be pre-populated with values from Coeus test system? What is the source of these values (NIH CRISP?). Would some insitituions want to allow free text? Does area of science value on committee limit the type of protocols that can be reviewed by that committee? Is there any relationship between area of science in IRB and science code in proposal development (I think not)? Should there be?