Kuali Coeus Implementation: IRB Progress Report

October 7, 2013
IRB Presentation Outline

- Current State Documentation
- Future State Process Development
- KC-IRB24 Protocol Development-Submission Process
  - Process Diagram
  - Data Assumptions
  - Rice Tables
  - Roles
  - Process Gaps
- Integration Assumptions
- Legacy Data Assumptions
- Current Process Gap List
IRB Contributors

• Project Team
  – Jim Poteracki, Lead Analyst
  – Rachael Hilliker, Analyst

• Business Unit ORA-HRPP
  – Kristen Burt, Interim Director, HRPP
  – Judy McMillan, HRPP Manager, Human Research Liaison Program
  – Rebecca Gore, HRPP Manager, Institutional Review Board
## IRB Current State Documentation (21)

<table>
<thead>
<tr>
<th>Module</th>
<th>Process</th>
<th>Module</th>
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<tbody>
<tr>
<td>IRB</td>
<td>118 Designation</td>
<td>IRB</td>
<td>Meeting Minutes</td>
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<tr>
<td>IRB</td>
<td>Adverse Event and Unanticipated Problems</td>
<td>IRB</td>
<td>Non Compliance</td>
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<td>Agenda Creation</td>
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<td>Online Project Review</td>
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<td>PI by Special Permission</td>
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<td>Alternate Exempt Review</td>
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<td>Expedited Review</td>
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<td>Project Closure</td>
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<td>Full Board Review</td>
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<td>Renewal-Revision</td>
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<td>Initial Application</td>
<td>IRB</td>
<td>Subject Complaints</td>
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<td>Initial HRPP Review</td>
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<td>Termination-Suspension</td>
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<td>Inter-Departmental Regulatory Review</td>
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<td>Training</td>
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<td>IRB Committee Member Assignment</td>
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**MICHIGAN STATE UNIVERSITY**
## IRB Future State Development (16)

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<td>IRB01</td>
<td>HRPP Staff Initial Review</td>
<td>IRB15</td>
<td>Site Visit</td>
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<td>IRB03</td>
<td>IRB Committee</td>
<td>IRB16</td>
<td>Subject Complaints</td>
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<td>IRB04</td>
<td>118 Designation</td>
<td>IRB18</td>
<td>Online Review</td>
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<td>Project Closure</td>
<td>IRB19</td>
<td>Meeting</td>
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<td>IRB11</td>
<td>Suspension-Termination</td>
<td>IRB22</td>
<td>High Level IRB</td>
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<td>IRB12</td>
<td>Renewal-Revision</td>
<td>IRB23</td>
<td>Post Approval Monitoring</td>
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<td>IRB13</td>
<td>Non Compliance</td>
<td>IRB24</td>
<td>Protocol Development-Submission</td>
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<td>IRB14</td>
<td>UPIRSO</td>
<td>IRB25</td>
<td>Protocol Deviation-Violation</td>
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</tbody>
</table>

* Processes in bold type will be reviewed in Blueprint Workshops*
IRB Process Highlight
KC-IRB24 Protocol Development-Submission (slide 1 of 4)

**KC-IRB 24: Protocol Development / Submission – Future State**

1. **Start**
2. **Login to portal**
3. **Access to KC2**
   - **Yes**: 4. **Create new protocol (or copy existing)**
   - **No**: 3. **Request system access (KC)**

**Protocol Tab**

4. **5 Select Protocol Type (Required)**
5. **6 Enter Title (Required)**
6. **7 Select PI (Required)**
7. **8 Select Organizations**
8. **9 Select Funding Sources**

1/3
IRB Process Highlight
KC-IRB24 Protocol Development-Submission (slide 2 of 4)
IRB Process Highlight
KC-IRB24 Protocol Development-Submission (slide 3 of 4)
IRB Process Highlight
KC-IRB24 Protocol Development-Submission (slide 4 of 4)

**KC-IRB 24: Protocol Development / Submission – Future State**

- **PI (Researcher)**
  - 29 Questionnaire: materials of human origin? (3/3)
  - No -> 31 Questionnaire: radiation use?
  - No -> 33 Questionnaire: controlled substances?
  - No -> 35 Questionnaire: use of human embryos?
  - No -> Stop

- **HRPP Administrative Office**

- **Other Departments/Units**
  - 30 Notification: materials of human origin
  - 32 Notification: radiation use
  - 34 Notification: controlled substances
  - 36 Notification: use of human embryos

* Questionnaire: affirmative response to specific question(s) trigger notification to various departments or units (e.g., Environmental Health and Safety - controlled substances, materials of human origin, and/or radiation use or Office of Regulatory Affairs - use of human embryos). The system may send notifications to other departments or units and/or HRPP staff may send an ad hoc notification to a specific individual or department/unit.
Data Assumptions
KC-IRB24 Protocol Development-Submission

• Data needed for process initiation
  – Existing protocol (if used as template)

• Transactional data (both input and output)
  – Protocol type*
  – Title*
  – PI*
  – Organizations**
  – Funding sources**
  – Investigators and protocol role
  – Research staff and protocol role
  – Attachments and notes (as needed)
  – Responses to questions in Questionnaire(s)

• Data generated on process completion
  – Completed protocol for review
  – Notifications to administrative offices (if applicable)

*Required field for saving  **Only required if selected
Rice Tables

KC-IRB24 Protocol Development-Submission

- Parameters (45, including 4 shared)
- Validation Rules (93 out-of-box)
- Notifications (5)
- Other Configuration Items
  - Code Table configuration 40 (including 16 shared)
  - Special Configuration Items
    - Questions and Questionnaires
    - Notification templates
Roles Defined/Assigned
KC-IRB24 Protocol Development-Submission

• List of Roles
KC Predefined Roles and Permissions (out-of-box)

**Protocol Creator (All System Users)**
Create Protocol

**Protocol Aggregator**
Submit Protocol
Modify Protocol
Modify Protocol Permissions
View Protocol
Create Amendment
Create Renewal
Add Notes
Modify Any Protocol
Delete Protocol
Recall Document

**Protocol Viewer**
View Protocol

**Protocol Deleter**
Delete Protocol
Roles Defined/Assigned

- List of Additional Roles
  KC Predefined Roles and Permissions (out-of-box)

**Maintain IRB Questionnaire**
- Modify Questionnaire
- Modify Question
- Maintain Questionnaire Usage

**IRB Administrator**
- Create Protocol Document
- Create Committee Document
- Submit Protocol
- Modify Protocol
- Modify Committee
- Modify Schedule
- Maintain Memberships
- Maintain Minutes
- View Protocol
- View Minutes
- View Committee
- View Schedule
- View Agenda
- Administrative Correction
- Maintain Protocol Submissions
- View Restricted Notes

**IRB Administrator (Cont.)**
- Generate Agenda
- Generate Minutes
- Generate Schedule
- View Member Details
- Perform IRB Actions on Protocol
- Modify Questionnaire
- Modify Question
- Modify Correspondence Template
- Modify Batch Correspondence Detail
- View Protocol Online Review Comments
- Maintain Protocol Online Review Comments
- Maintain Protocol Online Reviews
- Perform Committee Actions
- Modify Notification Template
- Protocol Review Not Required
- Edit Protocol Billable
- Modify Protocol Submission
- Maintain Protocol Notes
- View Active Protocol Types
- Modify Notification
- Create or Modify Research Areas

**IRB Reviewer**
- View Minutes
- View Committee
- View Schedule
- View Agenda
- View Member Details
- View Questionnaire
- View Question
- View Correspondence Template
- View Batch Correspondence
- View Notification Template

**Modify All Protocols**
- Create Any Renewal
- Create Any Amendment
- Submit Any Protocol
- Maintain Protocol Review Comments
- Maintain Protocol Related Project
- Maintain Any Protocol Access
- Add Any Protocol Notes
- Modify Any Protocol
Roles Defined/Assigned

• List of Additional Roles
  Out-of-box Derived Roles (based on relationship to document)

**Active Committee Member**
View Committee

**Active Committee Member on Scheduled Date**
View Schedule

**Active Committee Member On Protocol**
View Protocol

**IRB Unit Correspondent**
(Permissions determined by aggregator)

**IRB Organization Correspondent**
(Permissions determined by aggregator)

**Category: Protocol Personnel**
- PI (Aggregator by default)
- CO-I (Viewer by default)
- Study Personnel (Viewer by default)
- Correspondent CRC (Viewer by default)
- Correspondent Administrator (Viewer by default)

**Category: Protocol Affiliate Type**
(Permissions determined by aggregator)
- Faculty
- Non-Faculty
- Affiliate
- Student Investigator
- Faculty Supervisor
Roles Defined/Assigned

- List of Roles

  IRB Nested Roles (made up of grouping several roles together)

HRPP Staff
(IRB Administrators, HRPP Administrative Assistant, Human Research Liaisons)
IRB Administrator
Modify All Protocols
IRB Reviewer
Plus Permission: Modify Protocol Permissions

HRPP Management
(HRPP Managers, HRPP Director)
IRB Administrator
Modify All Protocols
IRB Reviewer
Maintain IRB Questionnaire
Plus Permissions: Modify Protocol Permissions,
Maintain KRMS Agenda, Blanket Approve Protocol Document, Blanket Approve Committee Document

IRB Chair
IRB Reviewer
Protocol Viewer
Plus Permission: View Restricted Notes
Roles Defined/Assigned
KC-IRB24 Protocol Development-Submission

• Consequence: who has access to what information for KC-IRB24
  – IRB Administrators will have access to all protocols, committee documents and online review documents to view, modify, delete, recall, and submit the document and attachments as well as take other protocol, committee, and/or online review actions.
  – Department and College Administrators will be able to perform the actions associated with the permissions assigned by the Aggregator.
  – PI will be able to view, modify, delete, recall, and submit the protocol and all related documents as well as take other protocol actions.
  – Individuals on the workflow route will receive an FYI notification.
  – Any persons added to the protocol as Aggregator will be able to view, modify, delete, recall, and submit the protocol and all related documents as well as take other protocol actions.
  – The person creating the protocol will automatically get the role of Aggregator.
  – Other users added to the protocol through the permissions tab, will have either Protocol Viewer, Aggregator or Deleter.
Potential Process Gaps

KC-IRB24 Protocol Development-Submission

- No means to check training for all individuals listed on a protocol
- No means to apply for a “118 designation” to a research project
- Attachments cannot readily be associated with transaction type
- No instruction materials nor web application tips for PI prior to the PI beginning the application
- KC does not populate a list of forms or attachments needed by the PI based on answers to the application/questionnaire
- A summary list of questions that need to be completed with hyperlinks to the specific questions is not provided
- No signature page specific to review level (exempt vs. expedited and full board)
- KC does not generate a list of consent form reminders based on answers to the application/questionnaire (e.g. include compensation in consent)
IRB Integrations

• KC Modules
  – Conflict of Interest (COI)
  – Preaward
  – Award

• Kuali Foundation Products
  – Kuali Rice

• MSU EBS Systems
  – SAP-EDW, OOI
  – Business Intelligence (BI)
  – Student Information System (SIS)

• MSU Legacy and Supplemental Systems
  – SABA (IRB Training)
  – Regulatory Websites
  – Clinical Research Management System (CRMS)
IRB Legacy Data Assumptions*

• What data are needed within application?
  – Sponsor data from
    • OSP/CGA Agency Table
    • HRPP FileMaker Pro
  – Person data from SAP-EDW and other appropriate university systems (e.g., SIS)
  – Unit and unit hierarchy data from OOI
  – HRPP performing organizations sites from FileMaker Pro
  – IRB training status from SABA

• What data are needed electronically?
  – All active IRB projects
  – Committee meeting materials
  – Reviewer data
  – Person data available nightly via batch process from SAP-EDW, and other appropriate university systems

• What data are needed in archive?
  – IRB records must be retained for at least three years after completion of research

• What data can be disposed?
  – To be determined

*Note: data conversion has not yet been discussed
## IRB Potential Gap List – “Must Haves” (12)

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<tbody>
<tr>
<td>No “Case Manager” data field; which allows for the ability to identify, track and notify the case manager (IRB Administrator)</td>
<td>No display of summary information (e.g. PI, level of review, status) for each record in the system</td>
</tr>
<tr>
<td>PI cannot enter or display review comment responses in-line with comments entered by HRPP staff or reviewers</td>
<td>No Administrative Attachments tab to permit the uploading of review attachments at any point in the protocol lifecycle</td>
</tr>
<tr>
<td>KC does not allow for a real time online review and therefore view ability/accessibility of online review and comments are determined only by HRPP staff action</td>
<td>No Administrative Tab (e.g. HRL, minutes) where documents can be uploaded for view by HRPP staff and Reviewers, but not PIs</td>
</tr>
<tr>
<td>HRPP staff cannot easily view previous versions of attachments to identify changes made as part of an renewal/amendment</td>
<td>Inability to create a unique identifier (e.g. Guest ID) that allows an individual to be listed on the application as an investigator or study personnel</td>
</tr>
<tr>
<td>PI, Reviewer, or HRPP staff, while reviewing an amendment, cannot view original protocol information</td>
<td>Same area of the protocol cannot be modified at the same time (e.g. generation of two amendments affecting same area of protocol)</td>
</tr>
<tr>
<td>PI, Reviewer, or HRPP staff do not have ability to view attachments associated with each transaction</td>
<td>PI should not be able to modify initial application once submitted to IRB. Need the ability to track changes</td>
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## IRB Potential Gap List – Statistics by Category

<table>
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<tr>
<th>IRB Gaps Category</th>
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<th>#</th>
<th>IRB Gaps Category</th>
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<tbody>
<tr>
<td>“Must Haves”</td>
<td>12</td>
<td>History</td>
<td>2</td>
<td>Reviewer</td>
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<td>118 Protocols</td>
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<td>HRL Review</td>
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<td>Search/Report Capabilities</td>
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<td>Agenda</td>
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<td>Identifiers (MSU Specific Identifiers)</td>
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<td>Shortcut Keys</td>
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<td>Special Review</td>
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<td>Attachments</td>
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<td>Notifications</td>
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<td>Committee Membership</td>
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<td>Online Review</td>
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<td>Watermarks</td>
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<td>PI Communication</td>
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<td>Data Field</td>
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<td>Questionnaire</td>
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Total potential IRB “process” gaps (as of 10/3/2013) : 136
IRB Upcoming Activities

• KC Configuration
• Fit Gap Analysis and Proposed Action
  – Code change
  – Configuration change
  – Business process change
  – Ignore (no action on gap)
• Reporting / Data Security
• Workshop Preparations
## IRB Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>118 Designation</td>
<td>45 CFR 46.118 applies to applications to federal agencies that may involve human subjects but where definite research plans would not normally be set forth</td>
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<tr>
<td>COI</td>
<td>Conflict of Interest</td>
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<td>CRMS</td>
<td>Clinical Research Management System</td>
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<td>IRB</td>
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<td>Human Research Protection Program</td>
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<td>KC</td>
<td>Kuali Coeus</td>
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<tr>
<td>KFS</td>
<td>Kuali Financial System</td>
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<td>Kuali Rice</td>
<td>Kuali Rice, provides middleware suite of integrated products</td>
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<td>Principal Investigator/Co-Investigator</td>
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<td>SAP-EDW</td>
<td>SAP HR/Payroll Data contained within MSU’s Enterprise Data Warehouse</td>
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<td>Organization of Interest</td>
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<td>ORA</td>
<td>Office of Regulatory Affairs</td>
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<td>SABA</td>
<td>Learning Management System to be used in Future State for IRB Training</td>
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<td>SIS</td>
<td>MSU’s Student Information System</td>
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<tr>
<td>UPIRSO</td>
<td>Unanticipated Problems Involving Risks to Human Subjects or Others</td>
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