Kuali Coeus Implementation: IRB Blueprinting Workshop 4

KC-IRB 11: Suspension-Termination
KC-IRB 13: Non-Compliance
KC-IRB 14: UPIRSO
KC-IRB 16: Subject Complaints
KC-IRB 25: Protocol Deviation-Violation

December 3, 2013
Goals and Outcomes

• Goals
  – Obtain feedback on the proposed future state (e.g., to-be) business processes
  – Review the configuration settings and application roles which support the processes within KC
  – Review the data assumptions which have been made while drafting the future state business processes
  – Review identified gaps related to the processes and amend as needed

• Outcomes
  – Document feedback and action items gathered during the session; distribute to participants for review
  – Utilize the information gathered to further refine business processes, configuration settings, application roles, data assumptions, and gaps
Presentation Outline

• Future State Process
  ➢ KC-IRB 11: Suspension-Termination
  ➢ KC-IRB 13: Non-Compliance
  ➢ KC-IRB 14: UPIRSO
  ➢ KC-IRB 16: Subject Complaints
  ➢ KC-IRB 25: Protocol Deviation-Violation

• Data Assumptions
• Configuration Values
• Roles Defined/Assigned
• Potential Gaps
• Integrations
• Considerations
# IRB Future State Development

<table>
<thead>
<tr>
<th>Process #</th>
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</thead>
<tbody>
<tr>
<td>KC-IRB 1</td>
<td>HRPP Staff Initial Review Process</td>
<td>KC-IRB 15</td>
<td>Site Visit</td>
</tr>
<tr>
<td>KC-IRB 3</td>
<td>IRB Committee</td>
<td>KC-IRB 16</td>
<td>Subject Complaints</td>
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<tr>
<td>KC-IRB 4</td>
<td>118 Designation Process</td>
<td>KC-IRB 18</td>
<td>Online Review Process</td>
</tr>
<tr>
<td>KC-IRB 10</td>
<td>Project Closure Process</td>
<td>KC-IRB 19</td>
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</tr>
<tr>
<td>KC-IRB 11</td>
<td>Suspension-Termination Process</td>
<td>KC-IRB 22</td>
<td>High Level IRB Process</td>
</tr>
<tr>
<td>KC-IRB 12</td>
<td>Renewal/Amendment Process</td>
<td>KC-IRB 23</td>
<td>Post Approval Process</td>
</tr>
<tr>
<td>KC-IRB 14</td>
<td>UPIRSO</td>
<td>KC-IRB 25</td>
<td>Protocol Deviation-Violation</td>
</tr>
</tbody>
</table>

Red - processes presented today.
Blue – previous workshops. Grey-processes will not be covered.
Process Consolidation Discussion

- KC-IRB 11: Suspension-Termination
- KC-IRB 13: Non-Compliance
- KC-IRB 14: UPIRSO
- KC-IRB 16: Subject Complaints
- KC-IRB 25: Protocol Deviation-Violation

Processes are similar in nature:

- All are post approval activities
- All deal with potentially urgent situations
- Similar actions used to address reported issues; similar protocol disposition (similar pathway/similar outcome)
- Many of the potential gaps are shared between processes
Considerations / Discussion Topics

- KC-IRB 11: Suspension-Termination
- KC-IRB 13: Non-Compliance
- KC-IRB 14: UPIRSO
- KC-IRB 16: Subject Complaints
- KC-IRB 25: Protocol Deviation-Violation

  - Multiple notify IRB actions
  - Online review
  - Access to project history
  - Correspondence/Acknowledgement
KC-IRB 11: Suspension-Termination
KC-IRB 11: Suspension-Termination

**IRB Chair/Vice Chair/HRPP Director**

1. Notified of potential need for suspension or termination
2. Ad hoc notify Director of HRPP, Chair(s) and Vice Chair or appropriate committee to determine next steps
3. Notification received
4. Immediate action taken to suspend project?
5. Notify HRPP
6. Notification received
7. Notify IRB? (needed for future actions if protocol not in a state that allows action)
8. Notify IRB
9. KC-IRB 18 Online Review
10. Emergency meeting?
11. IRB notified of suspension
12. KC-IRB 18 Online Review
13. Add to Agenda
14. Manage review attachments (if necessary)
15. KC-IRB 19 Meeting Process

**HRPP Staff**

- Start
- Notify HRPP (needed for future actions if protocol not in a state that allows action)
KC-IRB 11: Suspension-Termination - Future State

IRB Chair/Vice Chair/HRPP Director

Pl (Researcher)

19 Notification of Suspension

21 Notification of Termination

23 Notification of IRB Acknowledgement

24 Need to go back to meeting?

Yes

18 Suspend

17 IRB Determination?

No suspension/termination needed

22 IRB Acknowledgement

Suspend

16 Manage review attachments (if necessary)

20 Terminate

Stop

No

2/3

1/3

1/3
KC-IRB 13: Non-Compliance
KC-IRB 14: UPIRSO
KC-IRB 14: UPIRSO

**KC-IRB 14: UPIRSO - Future State**

**PI**
1. Determines that an UPIRSO may have occurred
2. Is event urgent?
   - Yes: Implement change to eliminate hazards to subjects or others
   - No: Notify IRB initiated

**HRPP Staff**
3. Implement change to eliminate hazards to subjects or others
4. Verbally report event to IRB within 24 hours

**IRB Chair/Committee**
5. Notify IRB initiated
6. Notification of potential UPIRSO received
7. KC-IRB 18 Online Review
8. Clearly not a UPIRSO?
   - Yes: Notify HRPP staff
   - No: Immediate action required to protect subjects?
9. IRB acknowledgement
10. Notification received
11. IRB acknowledgement
12. Notification received
13. Immediate action required to protect subjects?
   - Yes: Suspend protocol?
   - No: Notification received
14. Suspend protocol?
KC-IRB 16: Subject Complaints
KC-IRB 16: Subject Complaints

**HRPP Staff**

1. Start
2. Notify IRB
3. Receipt & review of subject complaint
4. Notify IRB (if necessary)
5. KC-IRB 18 Online Review

**Researcher (PI)**

6. KC-IRB 14 UPIRSO
7. KC-IRB 13 Report of noncompliance
8. Potential Noncompliance?
9. KC-IRB 11 Suspend protocol
10. Suspend Protocol?
11. IRB acknowledgement
12. Add to agenda?
13. Notify HRPP staff
14. Notification received
15. IRB acknowledgement
16. Notification received

**IRB Chair/Reviewers**

17. Manage review attachments (if necessary)

**Future State**

- KC-IRB 14 UPIRSO
- KC-IRB 13 Report of noncompliance
- KC-IRB 11 Suspend protocol
- Notify HRPP staff

**Last Updated By:** Rachael Hilliker
**Last Saved:** 11/27/2013 2:48 PM
KC-IRB 16: Subject Complaints

1. KC-IRB 19 Meeting Process
2. KC-IRB 16: Subject Complaints - Future State
3. Reporter (Subject)
4. Researcher (PI)
5. HRPP Staff
6. IRB Chair/Reviewers

18. KC-IRB 19 Meeting Process
19. IRB makes determination (as needed)
20. Determines appropriate corrective actions (as needed)
21. Manage review attachments
22. Notifies PI of determination & corrective/protective actions (if required)
23. Need to go back to the meeting?
24. IRB Acknowledgement
25. Notification received

If the notification is received, the process moves to the IRB Acknowledgement, then stops.
KC-IRB 25: Protocol Deviation-Violation
KC-IRB 25: Protocol Deviation-Violation

**KC-IRB 25: Protocol Deviations/Violations - Future State**

**PI**
1. Notify IRB

**HRPP Staff**
2. Notification of potential deviation/violation
3. Online Review KC-IRB 18

**IRB Chair/Committee**
4. Potential UPIRSO? Yes
5. UPIRSO KC-IRB 14
6. Potential noncompliance? Yes
7. Noncompliance KC-IRB 13
8. Immediate action required to protect human subjects? Yes
9. Suspend protocol? Yes
10. Suspension/Termination KC-IRB 11
11. Potential deviation/violation? Yes/Possible
12. Notify HRPP
13. Notification receipt
14. IRB acknowledgement
15. PI Notified
16. Amend protocol? No
17. Renewal/Revision KC-IRB 12
18. Add to Agenda? Yes
19. Notify HRPP
20. Notification receipt
21. IRB acknowledgement
22. PI Notified
Data Assumptions

• Data needed for process initiation
  – An approved protocol
  – Urgent situation(s)

• Transactional data (both input and output)
  – Notification or report
  – Online Review/Issue Resolution
  – Amendment (if necessary)

• Data generated on process completion
  – Correspondence (if necessary)
  – Notifications
  – Site Visit (if necessary)
  – Corrective Action plan (if necessary)
Configuration Values

• Parameter Values 22 (3 are shared*)
• Validation Rules (93 out of the box*)
• Notifications 21 (out of the box)
• Code Tables 69 (26 are shared*)
• Special Configuration Items
  - Notification templates
  - Questions and Questionnaires

* Module-wide, not process-specific
Configuration: Code Tables

Submission Type Qualifier
1. Modification/Amendment/Revisions/Significant New Finding
2. Annual Scheduled by IRB
3. Contingent/Conditional Approval/Deferred Approval/Non-Approval
4. Eligibility Exceptions/Protocol Deviations
5. AE/UADE
6. Complaint
7. Deviation
8. Protocol-Related COI Report
9. Self-report for Noncompliance
10. Request for Eligibility Exception
11. Training Certification
12. Unanticipated Problems
13. DSMB Report
Roles Defined/Assigned

- List of 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

**IRB Reviewer**
- View Schedule
- View Question
- View Questionnaire
- View Agenda
- View Batch Correspondence Detail
- View Committee
- View Correspondence Template
- View Member Details
- View Minutes
- View Notification Template
Roles Defined/Assigned

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

* If the proposed code table configuration values are implemented, the above applicable values would reflect those changes.
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

• Consequence: who has access to what information?

– Reviewers will be able to view protocol information.
– Assigned reviewers will be able to perform online review associated work on the protocol.
– 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.
Integrations

• Other Kuali Coeus Modules
  – Conflict of Interest (COI)
  – Preaward
  – Award

• Other Kuali Foundation Products
  – Kuali Rice

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

• MSU Legacy Systems
  – SABA (IRB Training)
  – Regulatory Websites
  – Clinical Research Management System (CRMS)
Considerations / Discussion Topics

- KC-IRB 11: Suspension-Termination
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- KC-IRB 25: Protocol Deviation-Violation

- Multiple notify IRB actions
- Online review
- Access to project history
- Correspondence/Acknowledgement
## IRB Potential Gap List

### Agenda

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<tr>
<th>IRB Gaps</th>
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</thead>
<tbody>
<tr>
<td>KC - agenda explanations are not associated with protocols listed in meeting details section and notes regarding agenda explanations are not stored in protocols.</td>
<td>KC does not allow HRPP staff to view previous versions of attachments to identify changes made as part of an amendment or renewal with amendment. HRPP staff cannot determine which attachments are replacing originals and which ones are in addition to the originals.</td>
</tr>
<tr>
<td><em>( Applies to processes: 11, 13, 14, 16 and 25)</em></td>
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<td>KC does not have the functionality to show dates that a transaction was placed &quot;in agenda&quot;. Including &quot;closed&quot;, &quot;expedited&quot;, - business process requires each transaction being associated with an agenda date.</td>
<td>KC does not allow a user (HRPP staff, PI, or reviewer) to view attachments associated with each transaction (initial app, amendment, renewal, etc.). User is not able to easily discern which attachments are uploaded for each transaction.</td>
</tr>
<tr>
<td><em>( Applies to processes: 11, 13, 14, 16 and 25)</em></td>
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### Amendment

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<tr>
<td>KC does not allow the same area of the protocol to be modified at the same time-generation of two amendments affecting the same area of the protocol.</td>
<td>FM: HRPP staff uploads attachments on behalf of PI - process allows the staff to QC documents prior to uploading into the system; KC: PI (and/or HRPP staff) uploads documents - may be a labor intensive process to ensure correct documents were attached or uploaded by PI (QC review).</td>
</tr>
<tr>
<td><em>( Applies to processes: 11, 13, 14, 16 and 25)</em></td>
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### Archival

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<tr>
<td>Currently HRPP denotes in FileMaker the location of paper copies pertaining to specific protocols (i.e., box 2, shelf 33). KC does not have a data field or similar way to denote the location.</td>
<td>KC - no separate attachment location/no ability to upload review attachments at any point in the protocol lifecycle (no Admin Attachments tab).</td>
</tr>
<tr>
<td><em>( Applies to processes: 13 and 16)</em></td>
<td><em>( Applies to processes: 11, 13, 14, 16 and 25)</em></td>
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### IRB Potential Gap List (Slide: 2 of 7)

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<tr>
<td>FM provides for the ability to view and print just the approval docs (approval docs - any documents that need to be provided to the PI as part of the 'approval package'). <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td>KC does not allow for additional correspondences without a signature and signature is pre-populated and cannot be customized. <em>(Applies to processes: 11, 13, 14 and 25)</em></td>
</tr>
<tr>
<td>KC does not include an administrative tab (currently labeled HRL) where documents can be uploaded and be made viewable to HRPP staff and/or reviewers, but not PIs (includes data elements associated to the attachment). <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td>Correspondence cannot be modified on a &quot;case by case&quot; basis. <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>Case Manager</strong></td>
<td><strong>Case Manager</strong></td>
</tr>
<tr>
<td>KC does not allow for a signature choice on a case by case basis. In KC signatures are automatically populated from the correspondence template identified by the action. <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td>KC does not allow for QC and regeneration of system generated correspondence in the event of an error. <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td>KC does not have a data field for case manager which would allow the ability to track changes to case manager by date, to identify the recipient of notices regarding the protocol, and to generate reports on case manager workloads. <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Correspondence</strong></td>
<td><strong>Correspondence</strong></td>
</tr>
<tr>
<td>KC does not allow for free text to be entered by HRPP staff into correspondences. <em>(Applies to processes: 11, 13, 14 and 25)</em></td>
<td>KC does not allow correspondences to be added, deleted, or modified without custom coding. There are 28 existing correspondences in HRPP existing processes and only 9 correspondences OOB in KC. All of these will need to be modified and additional correspondences will need to be generated. <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
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<tr>
<td>Data Field</td>
<td>History</td>
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<tr>
<td><strong>FM: HRPP staff can select which template or correspondence to use for a specific action; in KC, a single template or correspondence is associated with a specific action.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>KC does not contain a &quot;demo project&quot; data field nor the ability to search on such a field.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>KC does not allow HRPP staff to select correspondence with or without a signature (FM provides greater flexibility in the use of watermarks).</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>KC does not capture and retain in history the date a reviewer was assigned to a protocol or data field for &quot;follow up required&quot;.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>In FM, correspondence is associated with a transaction type; KC - correspondence is associated with a specific protocol action.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>KC does not allow the business office the ability to determine the status options for a protocol (ability to identify status types related to business needs).</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>KC only allows HRPP staff to indicate specific approval language in action comments at time of determination action (not during pending action).</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>KC does not allow the HRPP staff the ability to select the status options for a protocol; KC status is programmed to an action.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>KC does not have a data field for identifying FDA regulated protocols (which may or may not have an IND or IDE number but may still fall under FDA regulations). KC does not allow for a search and report on FDA related protocols.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>KC does not allow anyone to see or print history of all review comments left over the history of an entire protocol (i.e., protocol summary report only shows most recent review comments) in a consolidated view (previous or next in submission details is required).</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>KC does not have a data field or mechanism for indicating when a protocol is part of a reliance agreement (defer to reliance IRB as determination).</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>KC does not provide the ability to see all comments associated with the protocol over its entire lifecycle or the ability to readily find which are associated with initial application and those associated with renewal/revision. In FileMaker, HRPP staff and reviewers may see unedited comments; however, PIs are not able to view comments until the record is marked as viewable.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
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</table>
## IRB Potential Gap List (Slide: 4 of 7)

<table>
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<tr>
<th>IRB Gaps</th>
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<tbody>
<tr>
<td><strong>HRL Review</strong></td>
<td>KC: multiple actions are often required or necessary to produce what can be accomplished in one action in FM. <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>KC does not have a tab or fields for the HRLs (Human Research Liaisons) to conduct and document site visits.</strong> <em>(Applies to processes: 13 and 25)</em></td>
<td><strong>FM ('running banner'):</strong> information is easily tracked and displayed to HRPP staff for each record in the system (initial app, renewal revision, comments, review): Committee, Category, Level of Review, Title of Project, PI, Location, Status, Date Submitted, Record Action, Last Full Review, Current Approval, Most Recent Action - that display is not available in KC. <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>Identifiers</strong></td>
<td><strong>In FM, a PI is not able to modify the initial application, renewal, or revision application once it is submitted to the IRB. In KC, information can be modified upon the Return to PI action. Need the ability to track changes within the project (e.g., questionnaire).</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>KC does not allow HRPP staff to assign a custom unique identifier for the initial application.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>Notification</strong></td>
</tr>
<tr>
<td><strong>KC does not allow for HRPP staff to free form enter the current location of the physical file (e.g., specific HRPP staff member's office).</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>Notifications cannot be modified on a case by case basis.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
<td><strong>Online Review</strong></td>
</tr>
<tr>
<td><strong>KC does not allow for real time interaction between reviewers, PI, and HRPP staff due to its transactional nature.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><strong>KC does not allow the entry or display of review comment responses by the PI inline with where the comments are entered by HRPP staff. PI must respond to comments as a note or attachment.</strong> <em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td>IRB Gaps</td>
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</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>KC does not retain the individual reviewer determination recommendation for approval/disapproval in the Online Review tab. (Applies to processes: 11, 13, 14, 16 and 25)</td>
<td>PI Communication&lt;br&gt;KC does not have a multi-purpose communication tool where investigators may submit comments, concerns, etc. through the human research (MSU) website and is accessed by HRPP staff in KC - Feedback Form (e.g., date, first name, last name, anonymous, group, direct message to, regarding, message, email address, follow-up). (Applies to process: 16)</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. (Applies to processes: 11, 13, 14, 16 and 25)</td>
<td>Reviewer Comments&lt;br&gt;KC does not allow for the ability to print off review comments left only by HRPP staff (currently all reviewer and HRPP staff comments would print off at once for current review). (Applies to processes: 11, 13, 14, 16 and 25)</td>
</tr>
<tr>
<td>KC does not permanently retain (e.g., Summary &amp; History) HRPP staff instructions/comments submitted to each reviewer (reviewer assignment). (Applies to processes: 11, 13, 14, 16 and 25)</td>
<td></td>
</tr>
<tr>
<td>KC does not allow HRPP staff to remove a reviewer from the protocol review, but still maintain a record of the review assignment (e.g. if the reviewer was unable to complete review on time). (Applies to processes: 11, 13, 14, 16 and 25)</td>
<td>KC - when a protocol is assigned to an agenda, the system does not allow the PI to add additional comments or upload attachments (various protocol actions 'locked' to the PI - including adding attachments and comments). (Applies to processes: 11, 13, 14, 16 and 25)</td>
</tr>
<tr>
<td>KC - HRPP staff and other reviewers cannot view reviewer comments until they are &quot;submitted&quot; by reviewer due to the transactional nature of the system (comment database, Review tab). (Applies to processes: 11, 13, 14, 16 and 25)</td>
<td>KC does not allow all of the review comments in a consolidated view within the display of &quot;review comments&quot; for each protocol. (Applies to processes: 11, 13, 14, 16 and 25)</td>
</tr>
<tr>
<td>KC - when a protocol is assigned to an agenda, the system does not allow the PI to add additional comments or upload attachments (various protocol actions 'locked' to the PI - including adding attachments and comments). (Applies to processes: 11, 13, 14, 16 and 25)</td>
<td>KC does not retain the original comment left by a reviewer separately if it is edited by HRPP staff. (Applies to processes: 11, 13, 14, 16 and 25)</td>
</tr>
<tr>
<td>IRB Gaps</td>
<td>IRB Gaps</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Search Capabilities/Reporting**                                        | KC does not allow for consolidation of comments for a particular IRB number lookup.  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| KC does not contain a data field for the PI's PID number nor a way to search protocols based on PID number and display hyperlinks to the applications.  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| KC does not have a Status tab (Status check: simple display - app type, type action, submitted, sent out, approval, letter sent, agenda date, case manager and each "r" or "l" links to the particular transaction; displays easy history).  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| FM: within each PI record, HRPP staff is able to see all protocols the PI is associated with (e.g., assigned as PI, Co-PI, etc); KC - display not available to the HRPP staff and they must navigate to specific search screens.  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| KC does not allow for customized searches for any field (or combination of fields) on any application (initial, renewal, amendment, etc).  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| KC does not allow for customized searches that will provide hyperlink to reviewer form (contact information).  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| FM - has an "Admin" tab with the following data fields: (comment, approval date with checkbox to select) - alteration of consent, waiver of consent, waiver of documentation, pregnant women or fetuses, neonates, prisoner, children, wards, diminished capacity, HIPAA, FDA regulated, investigational devices (SR/NSR), sponsor-investigator, institutional reliance agreements, individual investigator agreements, noncompliance, audit, federally funded, sites, other (KC - does not have an Admin tab nor a single location that collects all of this data).  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| KC does not allow for customized searches that will provide hyperlink to a specific record to display individual comments.  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
| PI database: unable to search for and report on all records - all records within the database (hyperlinks).  
  *(Applies to processes: 11, 13, 14, 16 and 25)*                        |
### IRB Potential Gap List (Slide: 7 of 7)

<table>
<thead>
<tr>
<th>IRB Gaps</th>
<th>IRB Gaps</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI database: inability to store and link attachments (hyperlinks).</td>
<td>Watermarks</td>
</tr>
<tr>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td></td>
</tr>
<tr>
<td>PI database: inability to link protocols.</td>
<td>KC does not allow for multiple watermarks to be on a single document.</td>
</tr>
<tr>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td>HRPP staff can easily search for and identify PIs in FileMaker.</td>
<td>KC does not allow for watermarks to be applied selectively to some</td>
</tr>
<tr>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td>documents and not to others.</td>
</tr>
<tr>
<td>Ability to perform multiple searches simultaneously with ability to</td>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
</tr>
<tr>
<td>access full protocol records.</td>
<td></td>
</tr>
<tr>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Shortcut Keys</strong></td>
<td></td>
</tr>
<tr>
<td>Shortcut keys are not available in KC as they are in FileMaker.</td>
<td></td>
</tr>
<tr>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td></td>
</tr>
<tr>
<td>KC does not provide a way for HRPP staff to access each listed</td>
<td></td>
</tr>
<tr>
<td>investigator's training record within protocols.</td>
<td></td>
</tr>
<tr>
<td><em>(Applies to processes: 11, 13, 14, 16 and 25)</em></td>
<td></td>
</tr>
</tbody>
</table>
Considerations / Discussion Topics

- KC-IRB 11: Suspension-Termination
- KC-IRB 13: Non-Compliance
- KC-IRB 14: UPIRSO
- KC-IRB 16: Subject Complaints
- KC-IRB 25: Protocol Deviation-Violation

- Multiple notify IRB actions
- Online review
- Access to project history
- Correspondence/Acknowledgement
<table>
<thead>
<tr>
<th><strong>Glossary</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Role</strong></td>
<td>Made up of granular permissions which enables users to access data or perform certain business functions</td>
</tr>
<tr>
<td><strong>Code Table</strong></td>
<td>Typically provides values for drop-down lists referenced by the application</td>
</tr>
<tr>
<td><strong>COI</strong></td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td><strong>Configuration Setting</strong></td>
<td>The initial arrangement of parameters, code tables, etc. that determines what the application will do and how its components will interact</td>
</tr>
<tr>
<td><strong>CRMS</strong></td>
<td>Clinical Research Management System</td>
</tr>
<tr>
<td><strong>HRPP</strong></td>
<td>Human Research Protection Program</td>
</tr>
<tr>
<td><strong>IRB</strong></td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td><strong>KC</strong></td>
<td>Kuali Coeus</td>
</tr>
<tr>
<td><strong>KFS</strong></td>
<td>Kuali Financial System</td>
</tr>
<tr>
<td><strong>Kuali Rice</strong></td>
<td>Kuali Rice, provides middleware suite of integrated products</td>
</tr>
<tr>
<td><strong>Notification</strong></td>
<td>A message which is delivered to the user based on some action the user has performed</td>
</tr>
<tr>
<td><strong>OOI</strong></td>
<td>Organization of Interest</td>
</tr>
<tr>
<td><strong>Parameter</strong></td>
<td>An externalized application variable, the value of which can be maintained through the User Interface</td>
</tr>
<tr>
<td><strong>PI/CO-I</strong></td>
<td>Principal Investigator/Co-Investigator</td>
</tr>
<tr>
<td><strong>SAP- EDW</strong></td>
<td>SAP HR/Payroll Data contained within MSU’s Enterprise Data Warehouse</td>
</tr>
<tr>
<td><strong>SIS</strong></td>
<td>MSU’s Student Information System</td>
</tr>
<tr>
<td><strong>UIPRSO</strong></td>
<td>Unanticipated Problem Involving Risk to Subject or Others</td>
</tr>
<tr>
<td><strong>Validation Rule</strong></td>
<td>A check built within the application to ensure the data necessary for the system to perform a function is present and/or appropriate</td>
</tr>
</tbody>
</table>