



## Administrative Process Improvement Project

### Institutional Review Board Submission Process – Final Report & Recommendations 5/1/2012

#### Overall Findings:

1. The AS IS is a broken process, in spite of many efforts. Based on data gathered this calendar year, 82% of submissions are returned for revision with either major or minor contingencies (see Table 1).
2. We have implemented some quick hits that will moderately improve things – these include revised forms, clearer instructions, and, at some point, additional online training opportunities.
3. As research effort and graduate enrollment grow, the impact on the IRB grows.
4. Current methods of maintaining IRB records (record retention requirements are 3 years from date of completion of research) are splintered.
5. Research Support Services is utilizing an Access database to monitor their internal processes and to manage many IRB records; researchers submit protocols via email; communications back from IRB are all manually generated through email. Given the size constraints of MS Access, this database will need to be replaced within a few years; that planning needs to begin now.
6. Given the need to replace the MS Access database, the team reviewed a series of options (see Table 2).

**Table 1. IRB Submission Data, 2012 to date**

Meeting Date	Full Board Protocols					Determinations	Exempt Protocols	Total Protocols
	Original Protocols Approved	Revised Protocols Approved	Major Contingencies	Minor Contingencies	Total to Full Board			
1/19/2012	2	1	5	6	14	0	7	21
2/2/2012	2	0	5	1	8	0	5	13
2/17/2012	3	5	5	5	18	1	6	25
3/1/2012	2	3	7	4	16	8	6	30
3/23/2012	1	9	5	5	20	5	3	28
4/5/2012	0	2	3	8	13	1	4	18
<b>Totals:</b>	<b>10</b>	<b>20</b>	<b>30</b>	<b>29</b>	<b>89</b>	<b>15</b>	<b>31</b>	<b>135</b>

As of April 18, 2012

**Table 2. Management of IRB Submission Process & Records Management – Review of Options**

SYSTEMS	PRO	CON	Final Team Recommendation
<b>ACCESS DATABASE (N-IRB)</b>	Own; have designed & refined database	Much of process (Communications & approvals) take place outside of Database; Eventually (2-3 years) will not sustain volume of records	Replacement planning needs to begin now
<b>UMDRIVE</b>	Own – primarily for document sharing purposes	Only meets portion of needs; May Change product	Not appropriate for this process
<b>MATRIX</b>	Own – primarily for workflow, document imaging, sharing & retention	Still requires paper & manual handling/ long time to implementation	Not appropriate for this process
<b>BANNER</b>	Own	No IRB module	Not appropriate for this process
<b>PURCHASE – ‘IRB Manager’ was reviewed by team</b>	Rely on ‘expert’ to maintain currency with every change in regulations; provides rich data w/dashboard; incorporates records management; automated communications; flexible & self-customized	Cost; implementation time; any purchased program has some elements of inflexibility, although this appears to be a very flexible, customizable and adaptive system	Recommend detailed review and ITD assessment of IRB Manager
<b>BUILD YOUR OWN SYSTEM</b>	Own/Develop to customer specs/tech support/less initial cost/state changes/	Cost to support/tech support/train /allocation of people’s time/tech time to develop support/federal rate changes/has limits	Do not recommend – difficult to keep up with changing federal requirements
<b>ADD ADDITIONAL FTE</b>	Dedicate resource/flexibility Add/dedicated IRB prescreen specialist or database or ERA. Support questions of faculty & students	Cost/train/still may be dealing with database/human errors (duplicate, incomplete data)	Estimated additional 4.0 FTE needed to manage current volume of approx. 320 new submissions/yr. Team recommends 2.0 FTE devoted to IRB.

**Recommendation:** Therefore, the IRB Process Improvement Team recommends that the University evaluate and implement an off-the-shelf IRB management system. (The product ‘IRB Manager’ was reviewed by the team; it appears to meet our needs.)

**Analysis.** Because of the need to replace the MS Access database at some point, the implementation of an IRB management system is necessary. This should achieve a set of ‘technical’ goals - reduce incomplete submissions; automate workflow (reviews and approvals); automate communications; improve records management system; offer web-based access for researchers and board members; establish ability to self-audit and therefore contributes to compliance.

The extent to which that system improves desired ‘non-technical’ goals (allow more time for training, assistance to graduate students, in-depth pre-review of submission) depends to a large extent on the staff devoted to IRB. See Table 3 for a high-level summary.

**Table 3. IRB Goals & Staffing Levels**

	IRB Staffing		
	Status Quo (1.5 FTE)	Slight increase in staffing – 2.0 FTE	Any additional staffing
<b>Goals for the IRB Submission Process &amp; Records Management:</b>			
<b>Technical:</b> reduce incomplete submissions; automate workflow (reviews and approvals); automate communications; improve records management system; offer web-based access for researchers and board members; establish ability to self-audit and therefore contributes to compliance	Achieved	Achieved	Achieved
<b>Nontechnical:</b> reduce rework through improved training; increase depth of pre-reviews of submissions	Not achieved	Moderately achieved	Each incremental FTE added will further achieve nontechnical goals

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