

# Impact Analysis Case Study

(for discussion)

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# 2015

In late spring of 2015 MRAP was rolled out across the University. MRAP not only replaced the previous hybrid electronic/paper-based process of submitting animal use protocols for review and approval with a web-enabled solution, it became a cradle to grave solution for recording and tracking administrative tasks associated with the animal protocol process at the University.

## MRAP – My Research Animal Protocols

## Project Description

The web enabled MRAP system allows faculty members to submit their research protocols for internal review and approval. Reviews are coordinated and conducted on-line by Local Animal Care Committees (LACCs), including any required revisions to the protocol. MRAP leverages the existing HRIS, RIS and UTOAuth systems to automate the workflow, control access and delineate system roles. However, MRAP is much more than a review system.

Key features of the MRAP system:

- Web-enabled application form allows PIs to submit from anywhere there is web-access
  - Faculty may designate assistants, including students, to assist in the preparation of protocols
  - Link between training database and animal handlers provides auditable record of handlers' training
  - Link between the Research Information System and protocol form provides auditable record of the required peer review status of the underlying research
  - Ability to create amendments
  - Ability to create renewals
  - Change report to track changes between revisions and between amendments and renewals against the currently approved version of the protocol
  - Protocols may be distributed to reviewers as they are submitted
  - Reviewers input their comments on-line providing a clear audit trail
  - Reviewer comments are assembled in one place for review by the LACC and staff to facilitate the formulation of LACC recommendations
  - The number of approved animals is automatically added to the "Counting Tables"
  - Animal Counting Tables allow for accurate, up-to-date counting of approved, used and on-hand animal numbers
  - Agenda and Minutes functionality simplifies information distribution and record keeping
  - On-line committee member profiles assure compliance with CCAC regulations
  - Greatly improved security through the use of 2-factor authentication for "power-users"
  - Improved security by eliminating the need for paper versions of protocols
  - Access to protocols controlled by role, LACC and animal care facility
- Facility staff have instant up-to-date access to protocols relevant to their facility including training of associated animal handlers
  - Highly restricted access to animal care/veterinary notes
  - Access to all protocol related information in one on-line place, leading to improved monitoring capabilities
  - Post-approval review processes built on system information
  - Elimination of re-keying data into RIS

## Business/Technical situation

All research or teaching conducted with the use of live animals must receive approval from one of the University's Local Animal Care Committees (LACC). In addition there are ongoing monitoring requirements. Processes were carried out with a combination of paper, an insecure online document repository and email.

Applicants were required to download a form-fillable PDF. These forms were completed, scanned, uploaded and emailed to the Animal Care Manager in Research Oversight and Compliance Office. These protocols were then uploaded to DocuShare and held until two weeks prior to an LACC meeting at which point committee members were emailed that the agenda and protocol documents were available for review. Members then had to download the protocols and make their comments. Key pieces of information in the protocol (peer review status of the research, training of animal handlers) could not be easily verified. At the meetings reviewers provided their comments verbally and the Manager recorded these for return to the applicants. At the conclusion of the meeting, any paper copies of the documents were turned over to the Manager for destruction. Any amendments were presented on a separate form which meant that comments/decisions were made in the absence of the full protocol. Renewals were not permitted requiring applicants to complete a new protocol for ongoing research each year. Physical signatures by the Chair of the LACC and University Veterinarian were required once any required revisions had been made. Once approved, key data was re-keyed into RIS.

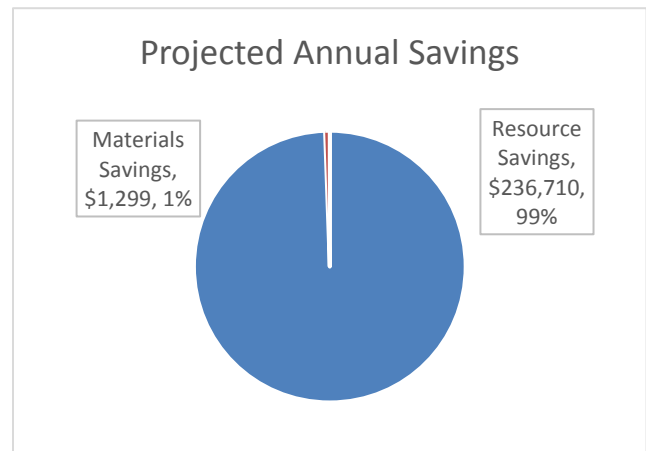
Additionally, there was no central point at which animal numbers could be viewed – relying instead on a once a year report. There was no tracking of animals from one protocol to another. Both of these features were key CCAC requirements. Animal care notes were kept in each facility, making access difficult for the University's regulatory veterinarian.

Purging of old protocols was a completely manual process. Post approval review was also a paper/email hybrid.

### Solution

In the spring of 2015 MRAP became the most recent RAISE project to go live. By moving all aspects of the protocol process on-line, MRAP provides a secure easily accessible environment for mission critical animal research information. Development of the MRAP solution commenced with an analysis of current practices, policies and previous CCAC monitoring reports. The resulting optimized processes were codified in MRAP system rules. The system provides a comprehensive and transparent audit trail of all transactions, simplifies document retention and retrieval, and facilitates compliance (key to retention of \$400 million in annual research funding). MRAP seamlessly integrates with HRIS, RIS and UTOAuth, automatically controlling access, eliminating data rekeying and provides PIs with real-time access to their animal protocol information.

### Projected Savings: \$238,009 annually



### Solution Results

Probably the most notable achievement of the team that put this system together is that I normally receive complaints about the degree of paperwork and regulations involved in animal work from my colleagues. Any introduction of a new system is normally a source of complaints, however even the most vocal critics around Pharmacy and Medicine seem to be satisfied customers. Professor Ian Crandall, Chair of the Medicine/Pharmacy LACC.

## Cost Savings, Service Enhancement & Risk Mitigation Analysis

Ref #	Activity Category	Activity Sub- Category	Transactions per year	Cost per unit	Total Savings	Savings Attributed to:
1.0	<b>Material Costs</b>	Paper use reduction		\$0.05	\$1,299	Divisions
2.0	<b>Resource Costs</b>					
2.1		Reduction in review costs (Original Protocols)	550		\$94,129	Divisions/ROCO
2.2		Reduction in writing time (Original Protocols)	550		\$99,834	Divisions
2.3		Eliminate re-keying of data (Original & Amendments)	550		\$3,527	ROCO
2.4		Access to data				Divisions/ROCO
2.5		Document storage and retrieval				Divisions/ROCO
2.6		Document destruction	550		\$766	Divisions/ROCO
2.7		Approval signatures	825		\$6,128	ROCO
2.8		Reduction in review costs (Amendments)	275		\$32,327	Divisions/ROCO
3.0	<b>Risk Reduction</b>					
3.1		External compliance				University
3.2		Improved data security				University
4.0	<b>Brand Equity</b>					University

Reference # provides detail and assumptions made to calculate the cost savings

### 1.0 Paper applications:

Number of Original protocols per year	550
Number of copies	5 (estimate not all reviewers printed)
Average # of pages per application	10 (estimate)
Photocopy cost per page	\$0.05 (paper/equipment depreciation/faculty & staff time)
Reduce volume by an estimated 90%	
<b>Total annual savings</b>	<b>\$1,237.50</b>

Number of Amendments per year	275
Number of copies	5 (estimate not all reviewers printed)
Average # of pages per application	1 (estimate)
Photocopy cost per page	\$0.05 (paper/equipment depreciation/faculty & staff time)
Reduce volume by an estimated 90%	
<b>Total annual savings</b>	<b>\$61.88</b>

### 2.0 Resource Costs – Assumes no increase in the number of protocols

#### 2.1 Reviewer time (Faculty & Staff):

##### Old system

Number of Applications per year	550
Time spent per original protocol	0.5 hour
Average faculty/staff salary or reviewers	\$130,000 (no benefit cost)
Number of paid reviewers per protocol	10
Hourly cost	\$69.15 (40 hrs/wk x 47 wks)
Total cost of reviews	\$190,160

**New system**

Number of Protocols per year	550
Projected % which are renewals	75%
Time spent per renewal	10 minutes
Total cost of reviews	\$96,031

**Total annual savings** **\$94,129**

If a system of designated reviewers is adopted in the future, annual savings could double.

**2.2 Writing time****Old system**

Number of Protocols per year	550
Hours per protocol	4
Cost per hour	\$69.15
Total cost of writing	\$152,128

**New system**

Number of Protocols per year	550
Projected % which are renewals	75%
Time spent per renewal	0.5 hour (only 2 sections require updating)
Total cost of writing	\$14,262

**Total annual savings** **\$99,834**

**2.3 Re-keying data**

Number of Original Protocols per year	550
10 minutes per Protocol	
Number of Amendments per year	100
(not all Amendment changes recorded in RIS)	
10 minutes per Amendment	
Cost per hour	\$31.91
<b>Total annual savings</b>	<b>\$3,527</b>

**2.4 Access to data**

The protocol application form links to a variety of databases, (PI Funding, Animal Handler Training, Approved SOPs) eliminating the need to search through files for mandatory information. University regulatory and review authorities have on-line access to documentation which was previously stored in each of the facilities. Central office and LACC members have access to animal numbers.

**2.5 Document retention and retrieval**

Protocol documentation is now stored in a secure on-line environment and is available to PIs, Review Committee Members and Staff. This eliminates the need for the storage of paper documentation and facilitates easy document retrieval.

**2.6 Document destruction**

To limit liabilities protocol documents are purged in accordance with the University' archiving policy. This task will be automated in MRAP.

Number of documents purged per year	550
Number of days (ORE & Vivaria)	3
Cost per day	\$255.32

**Total annual savings** **\$766**

## 2.7 Approval signatures

Prior to the introduction of MRAP, once the PI had completed any required protocol revisions, ROCO staff were required to track down LACC Chairs for a physical signature on the protocol document. This could result in substantial delays in protocol approval if the Chair was not readily available. In addition to the staff time costs in securing the signature, this imposed delays in the commencement of the animal research.

Number of documents approved per year (Originals & Amendments)	825
Estimated time	2 days per month
Cost per day	\$255.32
<b>Total annual savings</b>	<b>\$6,128</b>

## 3.0 Risk Reduction

### 3.1 External Compliance:

Monitoring visits conducted by the CCAC had raised serious concerns regarding tracking and access to accurate animal numbers. Had these concerns not been addressed by MRAP the University risked imposition of a "solution" by the CCAC under threat of removal of the University's *Certificate of Good Animal Practice*. In the event that the University's *Certificate* were suspended all of the University's Tri-Council funding would be frozen (\$130 million annually). MRAP also includes functionality for researchers whose animals are housed at a TAHSN hospital but whose funds are administered through the University, to submit a copy of their hospital approved protocol to the central ethics office. This enables tracking of expiry and renewals of the hospital protocols tied to University administered funds as required by the *Agreement on the Administration of Agency Grants and Awards by Research Institutions*. A variety of penalties are available to the Tri-Councils if the University were found to be in breach of this *Agreement* up to and including a freeze on all Tri-Council funding.

### 3.2 Security

By moving the entire review process on-line the need for paper copies, which can be inadvertently left lying around has been greatly increased. Access to data is controlled by user name and password and the data displayed is delimited by user role. For power-users, those with access to a large number of protocols, MRAP employs 2-factor authentication. In addition to a user name and password, the user must enter a secret PIN into a separate device (smart phone or dongle) which generates a one-time passcode synchronized to the user's id.

## 4.0 Brand Equity

MRAP provides researchers and administrators with an easy to use online hub for animal protocol information and processes. As the second component of the My Research systems, it builds on the previously released My Research Applications and moves the University closer to a comprehensive on-line one-stop-shop for research administration functions. Based on initial feedback from users from other institutions with online animal protocol systems, MRAP excels in comparison to their current system and other commercially available systems.