Electronic Protocol Review- Tales from the Trenches from 1st Time Users
Session # M102, Monday April 29, 2019

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Office of the Vice President for Research/ Office of Research Protections and Compliance

UMBC Campus founded in 1966

- Carnegie Classification: *Doctoral University – Higher Research Activity*
- UMBC is designated a Minority Serving Institution (MSI) since 2017
- Extramural Research Awards in FY'18: $85M
- Research Expenditures in FY'18: $76M

61 Major, 41 Minors and 31 Certificate Programs

- Physical and biological sciences, social & behavioral sciences, engineering, mathematics, information technology, humanities, visual & performing arts

24 PhD, 40 Master's and 22 Graduate Certificate Programs

- Natural and social sciences, engineering, information technology, public policy, arts and humanities, education, human services, and others

546 Full-time Faculty plus 292 Part-time Faculty

Student Enrollment, Fall 2017 – 13,767

- 11,260 Undergraduates, 2,507 Grad Students
- Average Freshman GPA 3.86

About Us

University of Maryland Baltimore County

Proposals, Awards, Subawards, COI and Protocols

- 927 Proposals (627 FY18 –includes legacy & 297 FY19 as Dec 2018)
- 887 Awards (66 Sub Awards)
- 350 Human Subjects (FY 2018 / ½ 2019)
- 20 Animal Protocols (FY 2018 / ½ 2019)

Protocols Implementation Phase, Began on 09/10/2018,

Protocols Go Live, Summer 2019 (IACUC with IRB to Follow)

- # of people who will work in the Protocols module =3 FTE
- # of people who will work solely devoted to Implementation = 0 FTE

kuali

UMBC is joining other USM institutions and installing **Kuali** – UMB, UMCP, UMCES, UB, UMUC, UMES, Towson University and Salisbury University.

A cloud based system, system-wide initiative annual license and thus becoming part of a USM-wide network. KualiCo https://www.kuali.co/

Advantages of a Collaboration with USM Institutions
    sharing of resources (for implementation and operation),
    cost savings to implement and run the Kuali system, and
    enhanced support of **multi-disciplinary and multi-campus integration of research**.

The Electronic System

Benefits

- We can manage all compliance areas in one place, including COI, IRB, and IACUC while having access to all Sponsored Programs areas.
- Kuali Protocols was recently redesigned with input from many universities
- The module focuses on the user experience. These usability improvements help higher education researchers spend less time on administration and more time on research.
- Administrators, chairs, and reviewers each have critical roles in mitigating risk and ensuring compliance with the protocols for human and animal research.
- Reduces the administrative burden on your compliance office and your research administrators. Protocol creation and review are made easier with intuitive navigation, configurable forms and smart reviewer tools for human and animals work. The cloud-based solution ensures our system is always up to date, without IT dependence.

The Electronic System

What we can accomplish in the system

- Manage both IRB and IACUC review processes with one solution and via one portal – one login and one view.(SSO)
- Create protocol templates that are more likely to be complete and ready for review on the first submission.
- Improve and streamline reviewer comment management and between researchers and reviewers.

How our electronic process helps

- Eliminate cumbersome and inefficient processes and reduce the amount of time and paper spent tracking protocols in multiple shadow systems. Kuali Protocols simplifies IRB and IACUC compliance management through one portal solution thoughtfully designed to improve the user experience. With Kuali Protocols you can now:
- Customize any part of a protocol without code or IT help with the easy Kuali Form Builder.
- Find reviewer comment references easily, and avoid having to search through the system, with field-level review commenting. See comments right in the form section where they are made vs. a summary list of references.
- View specific changes between versions.

Fit Gap Time

UMBC's Business Process Review Fit Gap Analysis Strategy – Protocols

Purpose of the fit/gap process:
 The functional fit/gap process is a tool to determine changes to the system, ensuring that your electronic system work for your institution.

How do you do this:
      Identify where gaps in functionality exist by comparing your current business process requirements to system capabilities.

Fit Gap

Strategy Steps for Fit Gap

1) Confirm that Kuali Protocols meets all current UMBC business processes/requirements
2) Identify all current business processes (create or formalize current procedures)
3) Identify functionality that enables improvements to current processes or updates your institution to current industry standards or regulations
4) Process changes (revising the business process to meet system requirements)
5) Prioritize ,Prioritize, Prioritize
6) Create a finalized assessment (fit/gap) document for your office and stakeholder

Tool Box Resources

- Weekly meetings (Zoom or Skype)
- Issue Log
- Google Drive (Box, Drop Box) File Sharing Tools
- Maximize productivity, coordination at a low Cost (Utilize all Staff members across campus that have vested, similar interest
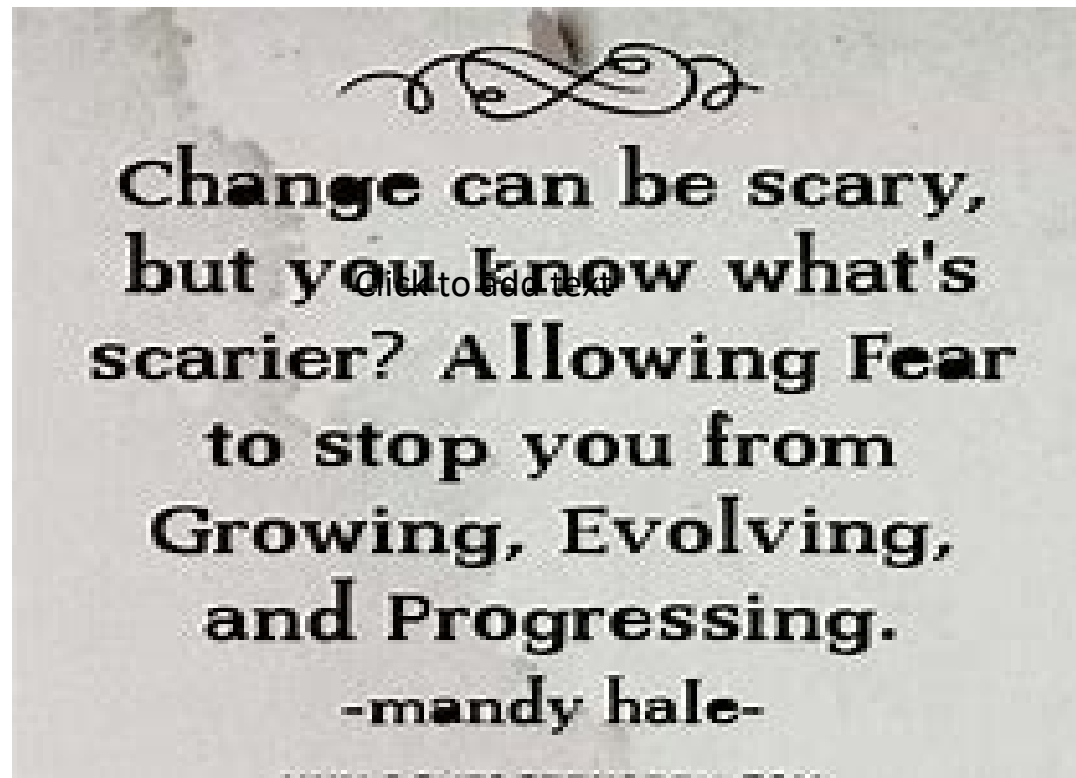- Maximize Efficiency for Data sharing

Benefits to Campus and Researchers

Campus Benefits

- Real time submissions
- Instant notification of submissions
- All submissions and protocols in one database

Researcher Benefits

- Instant notification of approval or resubmissions
- See where their protocol is in submission process
- All of their protocols in one place
- Automated notification of yearly updates

Campus Buy In

Change can be scary, but you know what's scarier? Allowing Fear to stop you from Growing, Evolving, and Progressing.
-mandy hale-

http://farm9.staticflickr.com/8260/8703026115_f53f5d18e3_z.jpg add text

Communication Strategies and Approach: Know your Audience

Getting the information out there

- Campus web page

- Email tags on launch date

- Have info sessions

- Talk one on one with folks you have

  identified as potential users

https://i.pinimg.com/736x/31/ea/d3/31ead379adb0a7fb735cba314990e7ac--teacher-stuff-teacher-humor.jpg

What to Tackle First
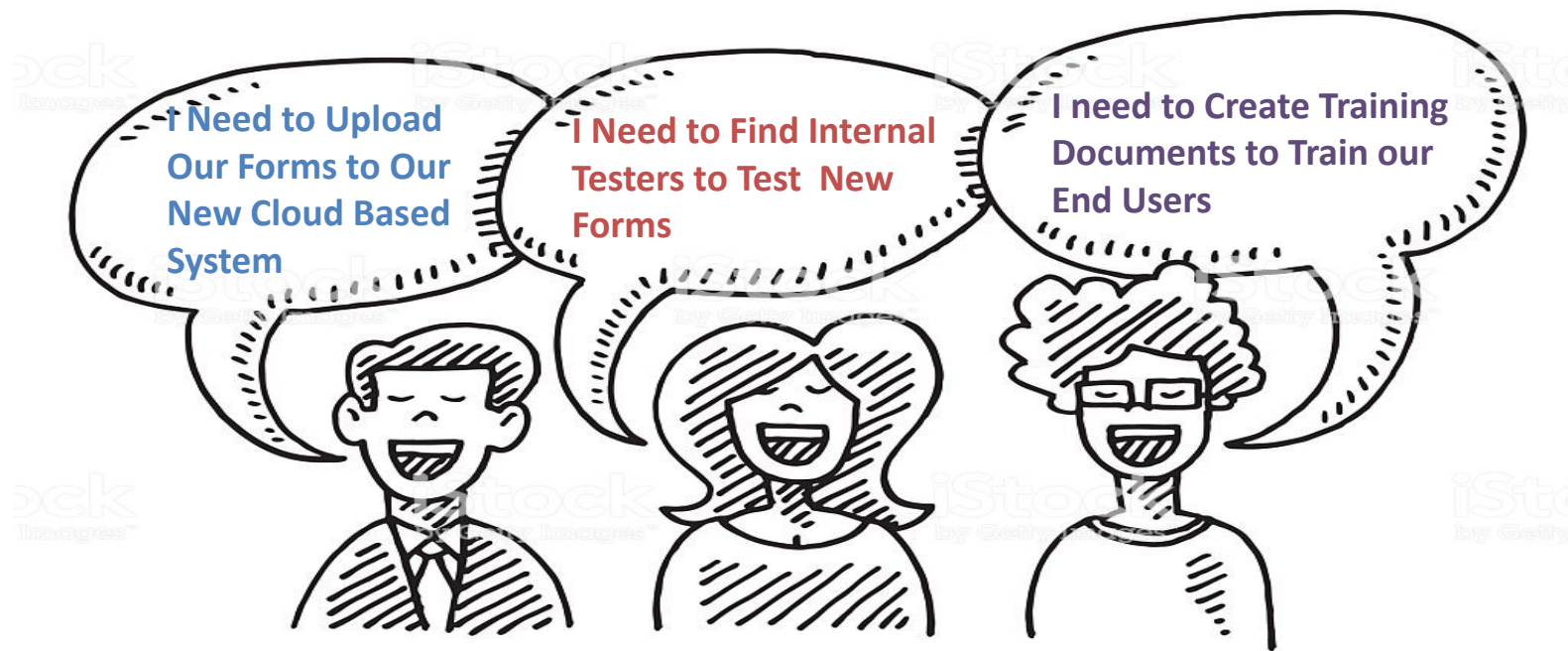
http://media.istockphoto.com/vectors/three-people-speech-bubbles-communication-drawing-vector-id523132585 add text

Protocols Implementation Schedule

Kuali Phase II- (Protocols)

- ➢ Input current protocol forms in to system to create on-line forms – Fall 2018 **Complete**
- ➢ Identify testing groups of IACUC stakeholders such as Department admins, Investigators, IACUC committee members Fall 2018/ Winter 2019 **Complete**
- ➢ Configure system to meet IACUC processes and SOPs **In Progress**
- ➢ Form testing and IACUC process review **In Progress**
- ➢ Develop training manuals **In Progress**
- ➢ Legacy data upload – Spring/Summer 2019
- ➢ IACUC protocols Go Live – Spring/Summer 2019
- ➢ IRB Configuration scheduled to begin Summer 2019

Input Protocol Forms
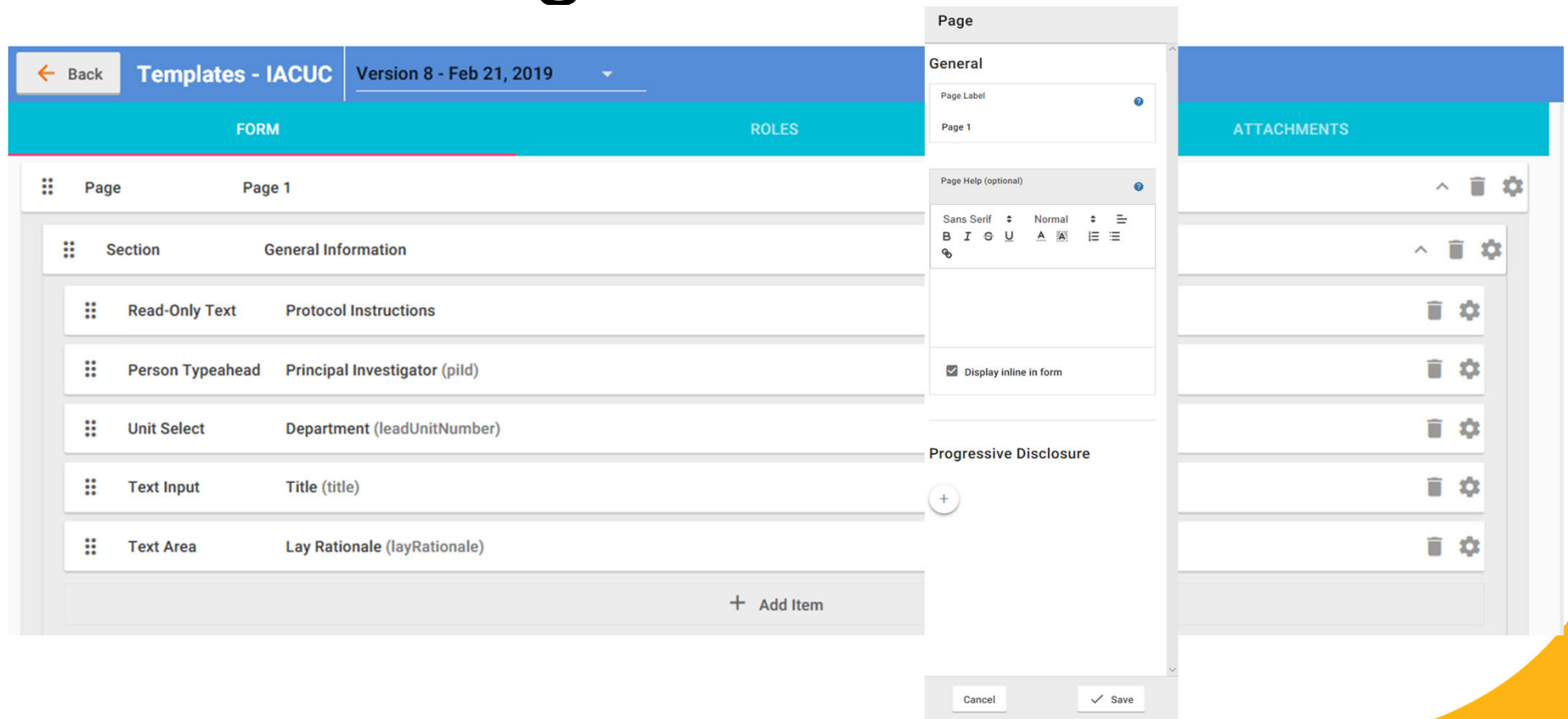
Current Animal Protocol (IACUC) Forms
- Animal Research Protocol Form
- Animal Import Form
- Animal Export Form
- Holding Protocol Request
- Protocol Annual Review Report (Final)
- Protocol Annual Review Report (Years 1 and 2)
- Protocol Closure Report
- Request for Minor Change/Amendment to an Animal Use Protocol
- Request for Significant Change to an Animal Use Protocol

Configure submission within Kuali structure

- How do paper process and electronic processes converge
  - Forms remain the same only the effort has changed
- What efficiency efforts can we identify
  - Time savings in multiple areas
    - Submission, review, approval
  - How best to serve investigator needs
    - Training is Key usually requiring visits to lab or office (personalized)
    - Group sessions with reserved rooms (block of hours)

Form Design Behind the Scenes

Issue Log

	Issue Log									
#	**Category**	**Module**	**Description**	**Priority**	**Status**	**Responsible**	**Jira**	**Next Steps**	**Resolution/Answer**	**Due Date**
1		IACUC	Kuali Use on the IPAD- Do you know if the portal is going to be more Apple Product friendly in the future.Example Right now when utilizing IPADS for training or Worshops, or speakingn engagements, when attempting to utilize the left navigation buttons, the display cover a large portion screen so i cannot selct or see options to the far right. I have screen shot,I can upload if you need a visual		Open	Kuali	RESPRO-1772		Currently mobile isn't fully supported, but that is planned for future development	
2		IACUC	Tim continues to have issues with PI impersonation. My Admin role in SBX kept being removed. Victor made adjustments, latest on 10/5/18 updating role to as a Technical Administrator in SBX. On 10/8/18, keep getting a 401 error message. Screen shots available for visuals		Resolved	Kuali			causing this and fixed it in SBX. A permanent change is needed from the engineers and the	
3		IACUC	Unit Progressive Searching is not currently available in the system.		Open	Kuali	RESPRO-1231		This is currently scheduled for development in 2019	
4		IACUC	Date Gadgets not rendering properly in the Person List		Delivered	Kuali	RESCOM-286		This is currently scheduled for development by the end of October.	
5		IACUC	Add Students to HR Feed		Ready for Validation	UMBC		Chanell indicates that the feed currently includes students. Retested. Chanell will confirm again.		
6		IACUC	There is a request to move the biohazard screening question to the Biohazard section, but that question was only added to the protocol to control if that section displays. What is the desired behavior for this question?		Answered	UMBC		We worked through this behavior.		

Who are the Testers in your Neighborhood

Look at personal Throughout Protocol Chain

- Administrators
- IACUC members
- Faculty and Researchers

Creation or updating of SOPs

- Current SOP
  - Look at current SOP's to determine what we can use
    - Pre KUALI
      - Submissions were done online
      - PI's had moved away from paper but now we need to update them with cloud based platform

- New SOP – how to get them fit post KUALI
  - Most required minor tweaks
  - Training was key to implementation

Training development and issues in training

- Master Training Document or "bible "

- Create "quick cards" that briefly summarize training info

- Find and secure space on campus to host training

- Training evaluation – how will this help us

Compliance buy in

In addition to training, meet Faculty/Departments on their own turf

- Schedule time at meetings
- Brief Chairs, Department Directors, Deans
- Spread the word via email and campus portals
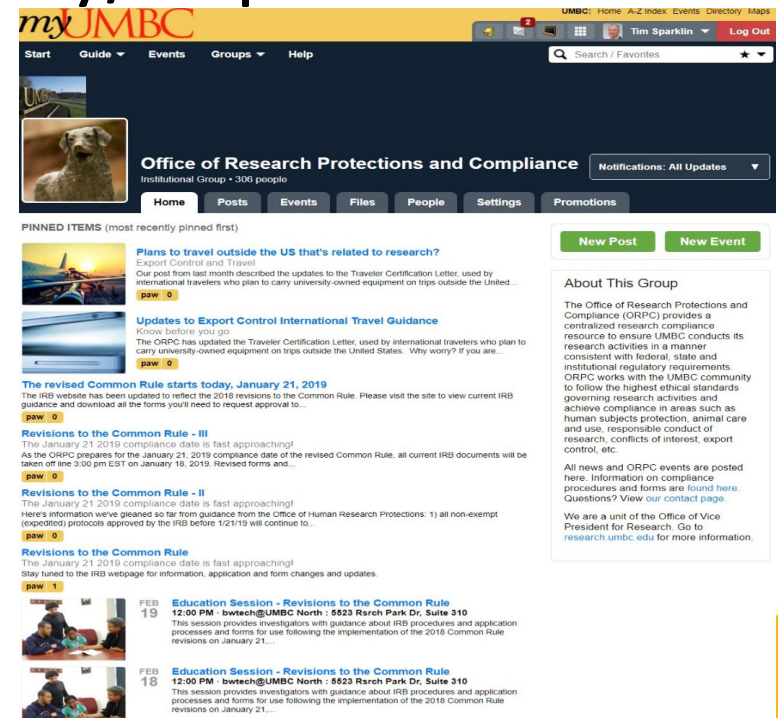
Legacy data

- **What to input**
  - IACUC – 20
  - IRB – 350
- **How to input**
  - Legacy paper versions different than system forms
- **Why to input**
  - Need to track currently active protocols until termination
- **Who to input**
  - Staffing issues –use current FTEs or hire students
  - Data quality concerns

Before Go Live - System Integration

- Getting system components to talk with another
  - Protocols, Awards, Proposal Development
- Ensure accurate training data uplink
  - CITI training
  - Bio Safety (Web net)
- Not all training data sources have active system links – while waiting need PI or compliance office inputting

ORPC11   ORPC1, 3/14/2019

Training Lookup Views

20 items retrieved, displaying all items.

Person Training CITI Record Id	First Name	Last Name	Email	Employee Number	CR Number	Curriculum	Group Id	Group	Score	Passing Score	Stage Number	Stage	Learner Id	Date Completed	Expiration Date	Registration Date	Name	User Name	Institutional User Name	Institutional Language
6623429	timothy	sparklin				Conflict of Interest mini-course	60339	UMBC Conflict of Interest Course	90	80	1		609531	09/07/2017 09:44 AM	09/06/2021 09:44 AM	06/14/2007 04:07 AM	sparklin timothy	HARPO@UMBC.EDU	DJ87283	
6623444	timothy	sparklin				Human Research	21661	Social/Behavioral Research Course	90	75	2		609531	05/06/2015 09:16 AM	05/04/2020 09:16 AM	06/14/2007 04:07 AM	sparklin timothy	HARPO@UMBC.EDU	DJ87283	

CONFLICT OF INTEREST

kuali

Sparklin, Timothy A

| ✕ Hide Menu |
| 🗹 Review Disclosures |
| ⚙ Configuration |
| 🔳 My Disclosures |
| 🚗 My Travel Log |

My Disclosures

ⓘ CITI-UMBC Conflict of Interest Course 1
Sep 7, 2017 - Sep 6, 2021

ⓘ Your disclosure expires in: 196 Days

⊕ Update Annual Disclosure

DISCLOSURE TYPE	LAST REVIEW	STATUS
Annual Disclosure	Sep 27, 2018	● Up to Date

Post Go Live - New vivarium and how Kuali Protocols integrate

- Capture protocol information (Having the SOPs in place)

- Non-centralized vs. centralized facility use and how to capture

- Investigator/facility personnel/IACUC member review and protocol adherence

https://fm.umbc.edu/projects/ilsb/

Questions and comments