“Lower than Low”-Volume Institutional Review Boards:

Lessening Challenges and Managing Risk

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March 11, 2019
SRA International Western/Southern Meeting

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Low-Volume IRBs and Supporting Offices

Low-Volume IRBs - IRBs that conduct less than 125 annual reviews and are typically housed in community-focused organizations lacking a research culture.

Laramie County Community College

- Less than 25 reviews per year
- Multiple stakeholders (research pool, research subjects, researchers, institutional offices, funder, regulators, community)
- Diversity and variety of protocols
- Growing research culture and increasing number of research-experienced employees
- Staff with multiple roles
- Roles with little redundancy

Low-Volume IRBs and Supporting Offices

University of Central Missouri

- 156 approvals in FY14
- 28% from Psychology department
- Approximately a dozen reports of IRB Noncompliance in 5 years
- Multiple stakeholders (research pool, research subjects, researchers, institutional offices, and regulators)
- Diversity and variety of protocols
- P&T pressure to publish

Presentation Objectives

Understand the risks faced by Low-Volume IRBs and their applicability to campus processes and practices.

(1) review too much, too quickly, with too little expertise, (2) minimal continuing review of approved research, (3) conflicts that threaten their independence, (4) little training for investigators and board members, and (5) little attention to evaluating IRB effectiveness

Develop an understanding of frameworks that can be used when implementing IRB process improvements.

Institutional processes and individual-level behavioral change interventions to align and comply with all of the laws, regulations, restrictions, policies, procedures, professional standards and established processes.

Ethical Framework: Nuffield Council on Bioethics

- Risk
- Precaution and Proportion
- Balancing
- Stakeholders
- Choice
- Vulnerable Groups
- Economic Benefits
- Behavior Change
- Intervention ladder

Local Context Will Always Matter

In the historical context of IRB review in the United States, there traditionally has been great tolerance for diversity of opinion among local IRBs, which have been encouraged to exercise their freedom to reach decisions based on local circumstances and preferences.

SACHRP Attachment A: Consideration of Local Context with Respect to Increasing Use of Single IRB Review

Local Context Will Always Matter

Because the research environment – at least in these sorts of studies – has drastically changed, and significant differences among sites and local subject populations can remain, SACHRP recommends that FDA and OHRP develop unified guidance that facilitates single IRB review, and assures adequate consideration of material local differences, for studies in which a common study design and unified review will tend to yield better science and greater subject safety.

SACHRP Attachment A: Consideration of Local Context with Respect to Increasing Use of Single IRB Review

Local Context Will Always Matter

…but material local variations must continue to be recognized and accommodated in study design and conduct.

Risk Assessment

		Impact				
		Insignificant	Minor	Moderate	Major	Severe
Likelihood	Certain	Moderate	High	High	Extreme	Extreme
	Likely	Moderate	Moderate	High	Extreme	Extreme
	Possible	Low	Moderate	Moderate	High	Extreme
	Unlikely	Low	Moderate	Moderate	Moderate	High
	Rare	Low	Low	Moderate	Moderate	High

LCCC (and UCM) IRB Review Risk Assessment

Challenges Facing Institutional Review Boards, Brown, Varmus and Friedman (oei-01-97-00194): (1) review too much, too quickly, with too little expertise

Score	Volume/Review Period	Type	Turnaround Pressure	Human Subjects IRB Expertise
1	**None**	**Exempt**	**Minimal** > 7 working days	**Extensive** Led an IRB > 3 years' experience on an IRB
2	**Minimal** 1-2 protocols	**Limited**	**Manageable** 5-7 working days	**Strong** IRB training Served on an IRB Conducted multiple research studies
3	**Moderate** 3-4 protocols	**Expedited**	**Firm** 3-4 working days	**Moderate** HS training Conducted study as a researcher
4	**Heavy** 5-6 protocols	**Full**	**Tight** 1-2 working days	**Some** HS training Conducted study as a student
5	**Crushing** 7+ protocols	**Full & Complex**	**Suffocating** Now	**None**

LCCC IRB Review
Risk Assessment

Concerns of IRB reviewers:

Score	Integrity of the researcher	Minimal Risk	Anonymity of the subjects	Security of the data	Vulnerable Group Issu Identified and Underst
1	**Full confidence** Extensive training and experience	**Full confidence** Well explained	**Full confidence** No Identifiers collected	**Full confidence** Extensive researcher training and experience Handling well explained	**Full confidence** Well explained
2	**Strong confidence** Ample training and experience	**Strong confidence** Sufficient explanation	**Strong confidence** Limited, **broad** identifiers collected	**Strong confidence** Ample researcher training and experience Handling sufficiently explained	**Strong confidence** Sufficient explanation
3	**Moderate confidence** Some training and experience	**Moderate confidence** Some explanation	**Moderate confidence** Limited identifiers collected	**Moderate confidence** Some researcher training and experience Some explanation of handling	**Moderate confidence** Some explanation
4	**Minimal confidence** Little training and experience	**Minimal confidence** Little explanation	**Low confidence** Identifiers collected	**Minimal confidence** Little researcher training and experience Insufficient explanation of handling	**Minimal confidence** Little explanation
5	**Unable to discern**	**Unable to discern**	**Protections Needed** Significant personal information collected	**Unable to discern**	**Unable to discern**

IRB Review
Process Improvements

Asking Effective Process Discovery Questions
theprocessconsultant.com

Managing Risk
Precaution and Proportion

Align policies and processes for risk appetite, regulations, and ethics:

- Risk avoidance
- Risk limitation
- Risk transference
- Risk acceptance

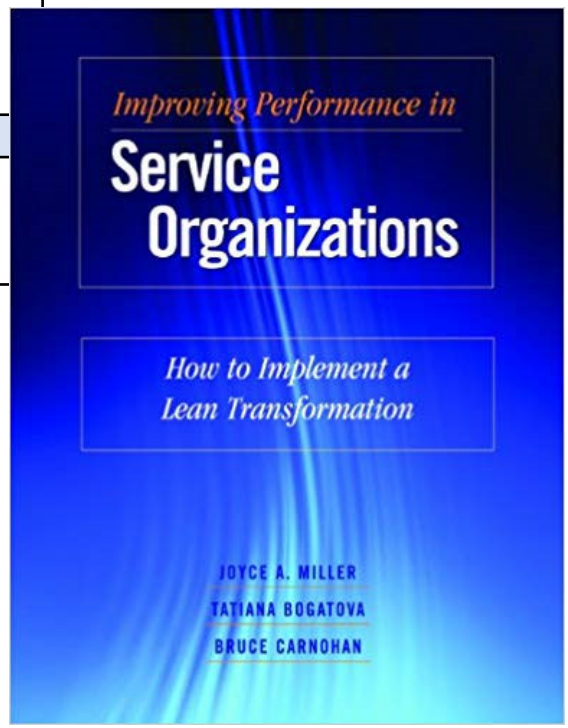
System Processes and Behavioral Change

- Know and build from existing:
  - norms
  - attitudes
  - intentions
  - cues to action/triggers
- Prepare for negative reactance to new expectations

Ajzen, I. (1991). The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes, 50, 179-211.*
Brehm, J. W., & Brehm, S. S. (1981). *Psychological reactance: A theory of freedom and control. San Diego,* CA: Academic Press.

Process Improvement Questions SWOT and Check Sheets

Strengths	Opportunities
Division of Institutional Effectiveness Sponsored Awards and Compliance	Common Rule Multiple Roles and Committee Service
Weaknesses	**Threats**
"Fossilized" process	Low Regulatory Awareness Low Volume of Reviews



Re-Designing the LCCC Request for IRB Review Form

1) Design process to educate and leverage individual choice:

- Change the external circumstances making compliant choices easier to make
- Improve individual's capacity to make compliant choices

2) Design process to increase clarity of, and confidence in, information reviewed by the IRB

Laramie County Community College Research Study Application for Permission to use Human Subjects in Research Form (Final 2009)

LARAMIE COUNTY COMMUNITY COLLEGE
INSTITUTIONAL REVIEW BOARD
RESEARCH STUDY APPLICATION FOR PERMISSION TO USE HUMAN SUBJECTS IN RESEARCH
Please type responses. Do not leave any item blank.
Use as much space as necessary for required explanations and descriptions

Principal Investigator(s) (PI): ***Attach curriculum vitae if not a full-time LCCC employee.***	
Phone:	Date:
Department:	
Institution:	
LCCC Sponsor (required if principal investigator is not a full-time LCCC employee):	
Title of Research Project:	
Please check purpose of project:____Class Assignment____Master's Thesis ___Doctoral Dissertation ___ LCCC Research ___Other (please explain):	
Please check the type of review being requested:____Exempt____Expedited____Full ***If requesting Exempt Review or Expedited Review, attach an explanation which includes justification using the definitions found in Section VIII of the LCCC IRB Human Subjects Research Manual.***	
Where will work be done?	
When will the research begin?	When will the research end?

CHECKLIST FOR RESEARCHER
Please check the appropriate column.

YES	NO	GENERAL ISSUES
		1. Are federal funds involved? If yes, sponsor's name:
		2. Are other external funds? If yes, sponsor's name:
		3. Is this application a renewal application for same research done one or more years ago and previously approved by this committee?
		4. Do you have
		a. any vested interest in any commercial enterprise associated with any aspect of the protocol?
		b. any other conflict of interest?
		Explanation required if the answer to either 4a or 4b is YES; use the EXPLANATIONS section of this application to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.
		5. Will this project require the supervision of a physician? **(Explanation required if YES; use the EXPLANATIONS section of this application.)**

CHECKLIST FOR RESEARCHER
Please check the appropriate column.

YES	NO	SUBJECT RELATED ISSUES
		6. Has the selection of subjects been equitable, with particular recognition of the special problems of research involving vulnerable populations such as pregnant women, children, prisoners, mentally or physically disabled persons, or economically or educationally disadvantaged persons? **(Explanation required if NO; use the EXPLANATIONS section of this application.)**
		7. Will the research impact any members of vulnerable populations such as pregnant women, children, prisoners, mentally or physically disabled persons, or economically or educationally disadvantaged persons? **(Explanation required if YES; use the PROTOCOL OF RESEARCH PROJECT Safety Measures section of this application.)**

YES	NO	N/A	CLASS ASSIGNMENT ISSUES
			8. Have the subjects been given a choice of the following: participate or do an equitable alternative assignment (i.e., book review, paper, etc.)? **(Explanation required; use the EXPLANATIONS section of this application.)**
			9. Have the subjects been offered an incentive (such as money, extra credit for the class, etc.) to participate in the research? **(Explanation required if YES; use the EXPLANATIONS section of this application.)**
			10. Will this research be conducted during regularly scheduled class time? **(Explanation required if YES; use the EXPLANATIONS section of this application.)**

YES	NO	INFORMED CONSENT/ASSENT ISSUES **A copy of the informed consent form must be attached to this application.**
		11. Will each subject, prior to the research, indicate informed consent/assent to participate by completing and signing a written form which includes:
		a. A description of the potential risks to the subjects including physical, psychological, emotional, social or spiritual well being? **(Explanation required if NO; use the EXPLANATIONS section of this application.)**
		b. A description of how the personal privacy of the subject will be protected? **(Explanation required if NO; use the EXPLANATIONS section of this application.)**
		c. A description of any incentives for the subjects and restrictions for receiving such incentives? **(Explanation required if NO; use the EXPLANATIONS section of this application.)**
		d. An indication that the subjects' participation is entirely voluntary and that they may withdraw at anytime? **(Explanation required if NO; use the EXPLANATIONS section of this application.)**
		e. A description of any debriefing that will be made available to the subjects? **(Explanation required if NO; use the EXPLANATIONS section of this application.)**

Laramie County Community College Research Study Application for Permission to use Human Subjects in Research Form (Final 2009) - continued

SUMMARY OF RESEARCH STUDY PROTOCOL

Project Description: Provide the following information: brief description of research methods, time required for single session, number of sessions, psychological or medical methods to be used, and research objectives or hypothesis(ses); if a survey instrument or other interview protocol is to be used, please attach a copy. Specifically address any proposed coercion or deception in the study design, including the rationale for such activities.

Number of Subjects: _____	**Age of Subjects:** ___Over 18 ___Under 18 **If under 18, indicate how parental consent will be obtained:**

Safety Measures: Outline specific safety controls.

- If applicable, indicate what OSHA requirements will be observed.
- If applicable, indicate what universal standards will be observed.
- If subjects may be pregnant women, children, prisoners, or mentally or physically disabled persons, indicate special precautions that will be observed.
- If physician's attendance is necessary, explain why.

Physician's Name and Contact Information (If Physician's attendance is necessary):

ATTACH THE COMPLETE RESEARCH STUDY PROTOCOL TO THIS APPLICATION.

REQUIRED EXPLANATIONS FOR CHECKLIST RESPONSES
Clearly indicate the item reference for each explanation.

REQUIRED SIGNATURES

I have read the LCCC IRB Human Subjects Research Manual and I certify that

- my proposed research study is in conformity with college policy, and
- I have completed the web-based training course offered by the National Institutes of Health [see http://phrp.nihtraining.com/users/login.php?l=3] within the past three years. (Attach a copy of your most recent training certificate of completion if it is not already on file in the LCCC IR Office.)

Principal Investigator *Date*

Attending Physician (if applicable) *Date*

Other Sponsoring Agency (if applicable) *Date*

LCCC Supporting Signatures

By signing below, individuals agree that they support the proposed research study and that the study is consistent with the mission, vision, and values of the college.

LCCC Sponsor (if applicable) *Date*

Division Dean or Department Head *Date*

Vice President *Date*

DISPOSITION BY LCCC IRB

___ Exempt ___Expedited Review ___Full Review

___Approved ___Tabled ___Disapproved

___Continuing Review Required

Next scheduled review is_____or upon completion of the study, whichever comes first.

Chair's Signature *Date*

Process Discovery Questions in Action

Principal Investigator(s) (PI): ***Attach curriculum vitae if not a full-time LCCC employee.***
LCCC Sponsor (required if principal investigator is not a full-time LCCC employee):
Title of Research Project:
Please check purpose of project: ___Class Assignment ___Master's Thesis ___Doctoral Dissertation ___ LCCC Research ___Other (please explain):
Please check the type of review being requested: ___Exempt ___Expedited ___Full ***If requesting Exempt Review or Expedited Review, attach an explanation which includes justification using the definitions found in Section VIII of the LCCC IRB Human Subjects Research Manual.***

Process Discovery Results

Researcher Qualifications

Human Subject Research Training:

Provide copies of certificates of training

Prior Research Study Experience:

Describe studies and your role

Reason for IRB review request:

□ LCCC research project
□ LCCC employee research project to meet degree requirements at external institution
□ Non-LCCC employee seeking access to LCCC students/employees as research subjects
□ Other (please describe)

LCCC Sponsor Name:

An LCCC research study sponsor required for all research studies conducted by non-LCCC employees or students and for all LCCC students, this person will be responsible for supervision of the project, compliance with the approved protocol, and ensuring all reporting is met.

Sponsor Signature:

Process Discovery Results

D. Level of review requested

1) Exempt from full review

To qualify for this level of review, the research must not be greater than minimal risk* and must fall into one or more of the exemption categories.

Minimal risk is defined by the federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

☐ Minimal risk met
(must be met to proceed)
Explanation:

Process Discovery Results

D. Level of review requested (cont.)

Select research study exemption category:

☐ a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, ***such as***:
i) research on regular and special education instructional strategies, or
ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: Conducting a study ***in*** an educational setting does not necessarily ***involve*** normal educational practice. Such studies may need further review, particularly if the studied practice is not ongoing (i.e. a one-time intervention) or when the questions or subject matter goes beyond the scope of the educational practice being studied.

Process Discovery Results

D. Level of review requested (cont.)

☐ b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, ***unless***:
i) the information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; ***and***
ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Note: Survey and interview techniques which include minors are not exempt.
Reminder: LCCC enrolls students who are younger than 18 – therefore surveys of LCCC students could reasonably include minors.

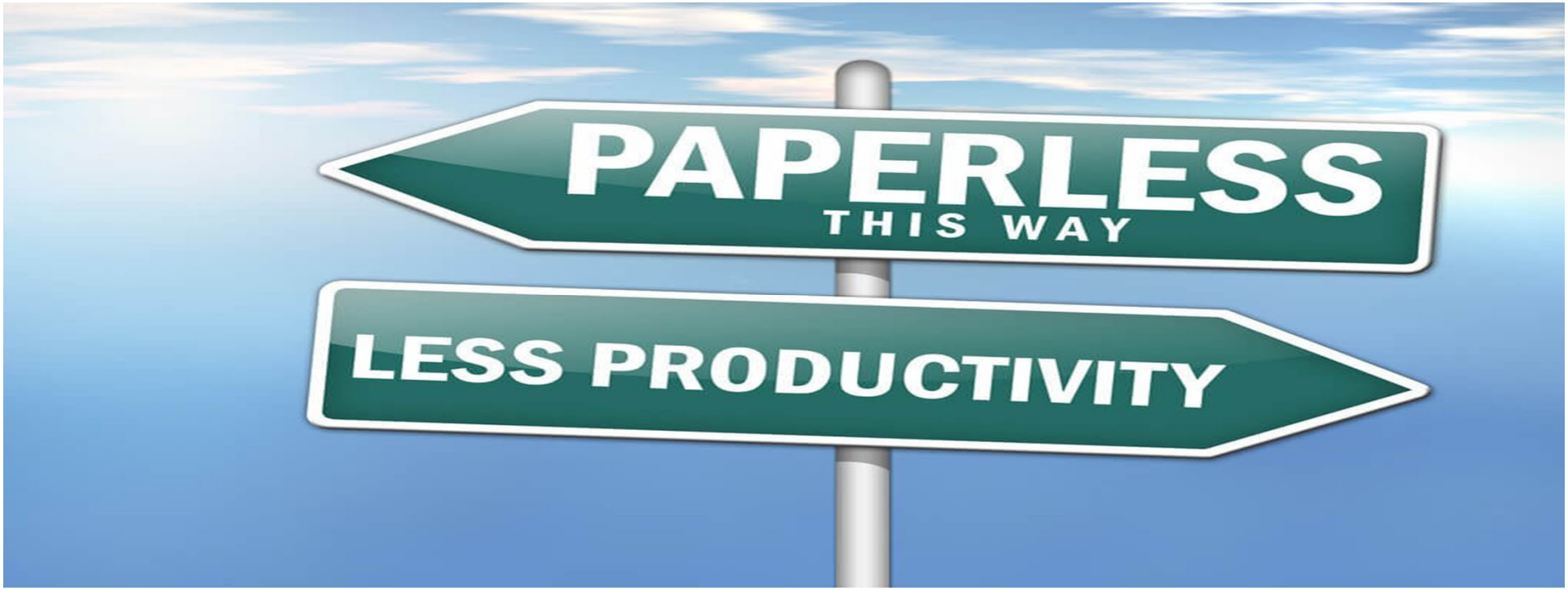
Process Discovery Results

D. Level of review requested (cont.)

☐ c) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are ***publicly available*** or if the information is recorded by the original investigator in such a manner that participants cannot be identified directly or through identifiers linked to the participants.

Note: The original collection must be unrelated to the proposed study.

☐ d) Other Category from 45 CFR 46



- H0surwrfro#p dqdjhp hqw#kdv#ehfrp h#wkh#qgxvwu|#
  vwdqgdug#Edqnhuw#) #Dp gxu/#5339,

- Vp do#qvwlwxwlrqv#uh#fkdoohqjhg#rshudwlrqdo|#e|#
  vp do#exgjhw/#qr#frqrp lhv#ri#fdsh#dqg#hvhdufk#dv#d#
  vhfrqgdu|#p lvvlrq#Juhhq/#533;,

- Vp do#qvwlwxwlrqv#uh#h{sorulqj#fuhdwlyh#dowhuqdwlyhv#wr#
  wkh#h0surwrfro#vwdqgdug

Economic Benefit

Cost comparisons

1. **Blackboard:** Mike Jeffries, administrator of UCM's Blackboard services, reports the cost of using Bb community modules is essentially free to the IRB. The cost for the community module is estimated at $50,000 but must be used in conjunction with the course delivery system. Another option small institutions may consider is the free use of CourseSites by Blackboard which may be accessed at https://www.coursesites.com. Although use is limited, it may provide those institutions that are interested another alternative for IRB operations."

2. **IRB Electronic Management Services:** IRBNet Collaborate - Contract includes unlimited number of users associated with our institution. The annual fee for our institution was quoted at $6,600.00 (USD).

3. **External Reviews:** Examples of fees that are charged for review of human research that is financially sponsored by industry or based at other institutions.

Mount Sinai School of Medicine

- Initial Reviews - $2,500
- Continuation Reviews - $1200
- Modification Reviews - $500
- External IRB Review One Time Administrative Fee - $575

Retrieved from http://icahn.mssm.edu/research/resources/program-for-the protection-of-human-subjects/researchers-palette/irb-review-fees

Seattle Children's

- Initial, Full Board Review: $1,500
- Renewal, Full Board*: $700
- Expedited Review or Exempt, Initial: $300
- Modification, Subcommittee: $250
- Modification, Full Board: $750

Retrieved from IRB fee policy http://www.seattlechildrens.org/research/support-services/institutional-review-board/forms-and-policies/policies/

Communication

Start Here

Institutional Review Board

The UCM Institutional Review Board reviews research applications and proposals involving human subjects to ensure the rights of the subjects are not violated and that the research conforms to the Code of Federal Regulations.

The Institutional Review Board meets every other Friday during the Fall/Spring semesters in Ward Edwards 1550 at 2 p.m. The 2018-2019 meeting dates are as follows; Fall-8/31, 9/7, 9/21, 10/5, 10/19, 11/2, 11/16, 11/30. Spring-2/1, 2/15, 3/1, 3/15, 3/29, 4/12, 4/26, and 5/3. Applications should be submitted no later than the Friday prior to the next scheduled meeting.

Please see the Application tab for updated applications. After September 1, 2017 these are the only applications that may be submitted. Any protocols submitted on the old applications will be returned for revision.

Steps for Protocol Approval

The following steps will guide you to protocol approval

1. Acquire a faculty advisor
2. Complete Responsible Conduct for Research (RCR) module of CITI training
3. Generate your research design and consent form (if needed)
4. Complete the correct application (all applications are found under "Applications" in the left navigation menu)
5. Submit your application to Blackboard along with corresponding materials i.e., consent form, surveys, permission from sites to conduct research.

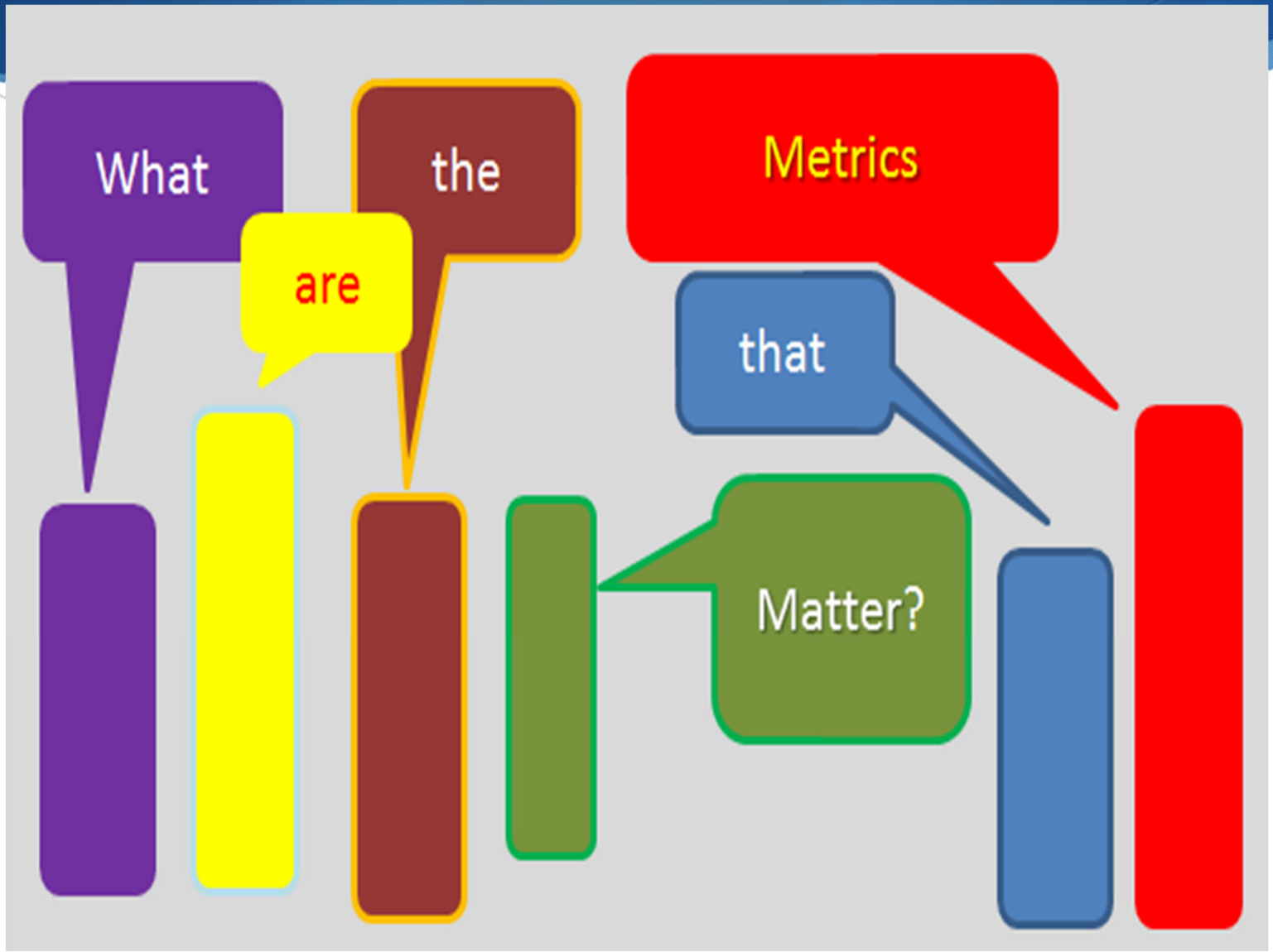
Contact Kathy Schnakenberg, the UCM Research Compliance Officer, with further questions at researchreview@ucmo.edu

Informed Consent Templates

Additional Human Subjects Resources

ITEM	LAST ACTIVITY	GRADE
Protocol Number	Nov 15, 2018 9:40 AM GRADED	933/1256/1263
Not human subject determination Assignment View Rubric	Nov 14, 2018 6:55 AM GRADED	1.00 /4
Exempt application Assignment View Rubric	Nov 16, 2018 2:49 PM GRADED	1.00 /4
Expedited application Assignment View Rubric	Aug 23, 2017 1:22 PM GRADED	1.00 /4
Full application Assignment View Rubric	UPCOMING	- /4
Revisions Assignment View Rubric	UPCOMING	- /4
CITI verification Assignment	Aug 24, 2017 2:11 PM GRADED	8/24/20
IRB Letters View Description	Feb 15, 2019 11:40 AM GRADED	Amd 2/15/2019
Consent View Description	Nov 19, 2018 9:37 AM GRADED	App 11/19/2018
Amendments Assignment View Rubric	Feb 15, 2019 10:58 AM GRADED	1.00 /4
Renewal Assignment View Rubric	UPCOMING	- /4
External IRB Approvals Assignment View Rubric	UPCOMING	- /4
Final Report Test	UPCOMING	- /16
Project Status Report Test	UPCOMING	- /10

Evidence



2011 Pre Blackboard Average number of days until review completed

242 total	UCM	NRN 2012 benchmark
Exempt	9.5	14
Expedited	13.4	15
Full	21	25

2012 Using Blackboard Community Average number of days until review completed

180 total	UCM	NRN 2012 benchmark
Exempt	12.7	14
Expedited	17.6	15
Full	24.4	25

2011 Pre Blackboard Average number of days until approved

242 total	UCM	NRN 2012 benchmark
Exempt	10.5	14
Expedited	18.9	35
Full	33.1	47

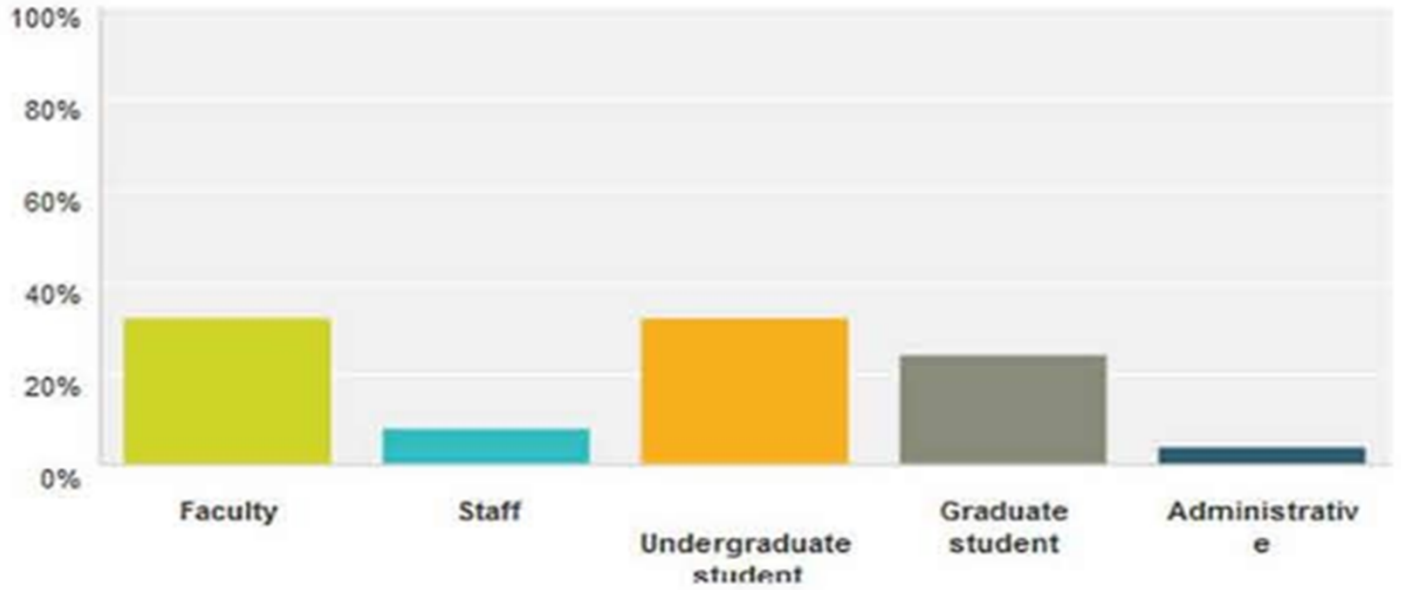
2012 Using Blackboard Community Average number of days until approved

180 total	UCM	NRN 2012 benchmark
Exempt	14.3	14
Expedited	21.0	35
Full	29.8	47

National Research Network benchmarks retrieved from http://irbnetresources.org/news/benchmark2012.html

What is your role at UCM?

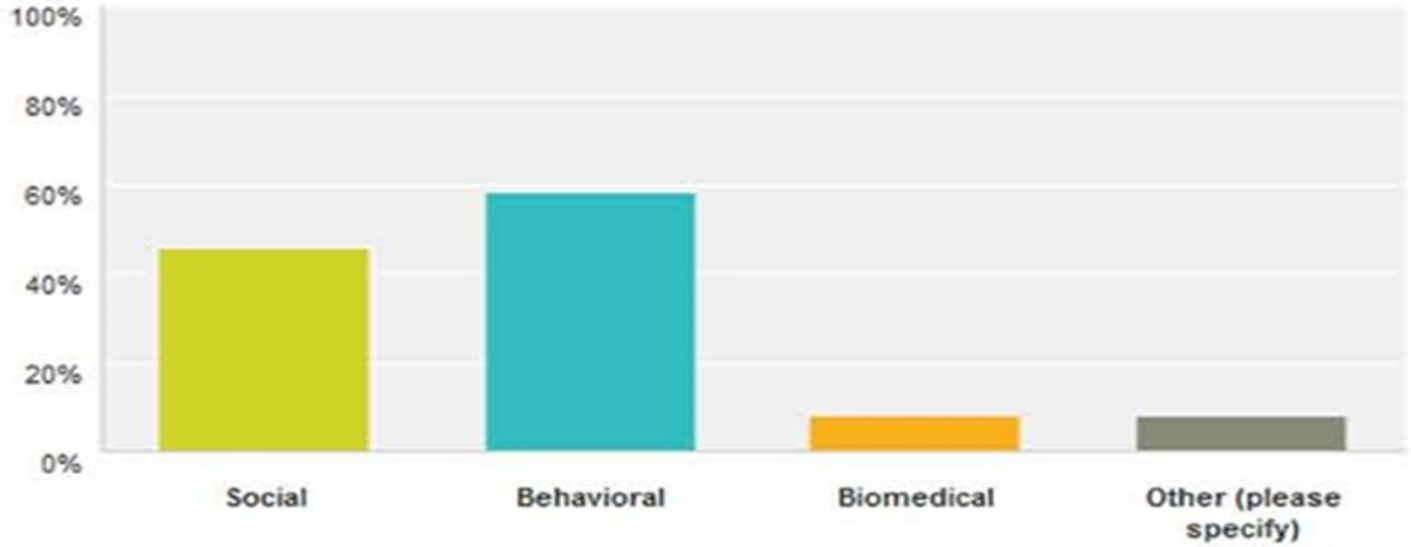
Answered: 25 Skipped: 0



Answer Choices	Responses	
Faculty	32%	8
Staff	8%	2
Undergraduate student	32%	8
Graduate student	24%	6
Administrative	4%	1
Total Respondents: 25		

What type of research do you primarily submit to UCM IRB?

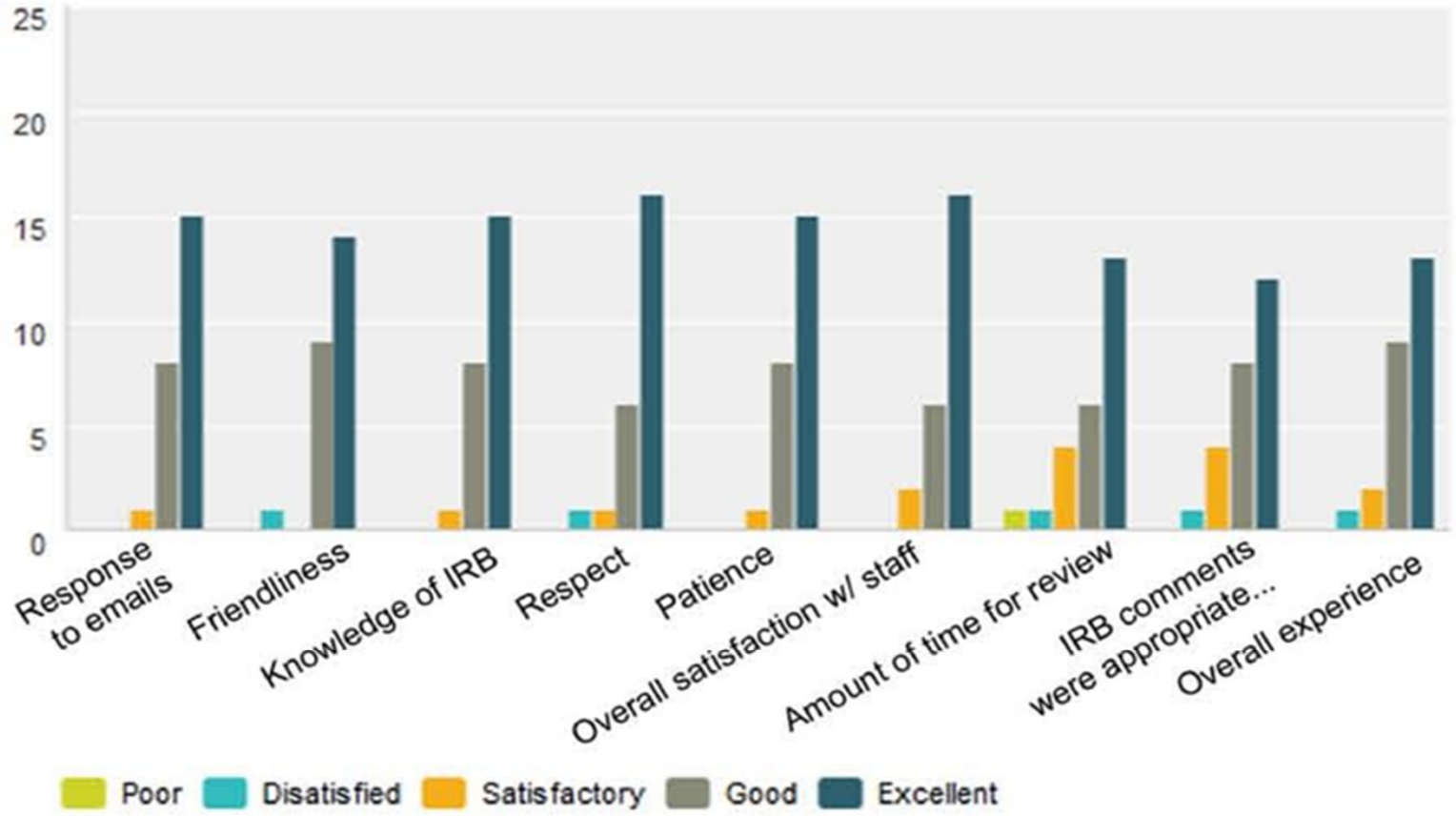
Answered: 24 Skipped: 1



Answer Choices	Responses	
Social	45.83%	11
Behavioral	58.33%	14
Biomedical	8.33%	2
Other (please specify) Responses	8.33%	2
Total Respondents: 24		

Rate on a scale from 1-5-5 being the highest and 1 the lowest

Answered: 25 Skipped: 0



What are things that IRB does well?

Answered: 6 Skipped: 2

Responses (6) | Text Analysis | My Categories

PRO FEATURE
Use text analysis to search and categorize responses; see frequently-used words and phrases. To use Text Analysis, upgrade to a GOLD or PLATINUM plan.

Upgrade Learn more »

Categorize as... | Filter by Category | Search responses

Showing 6 responses

Consistent format for proposals, whether full, expedited or exempt.
7/12/2013 10:17 AM View respondent's answers

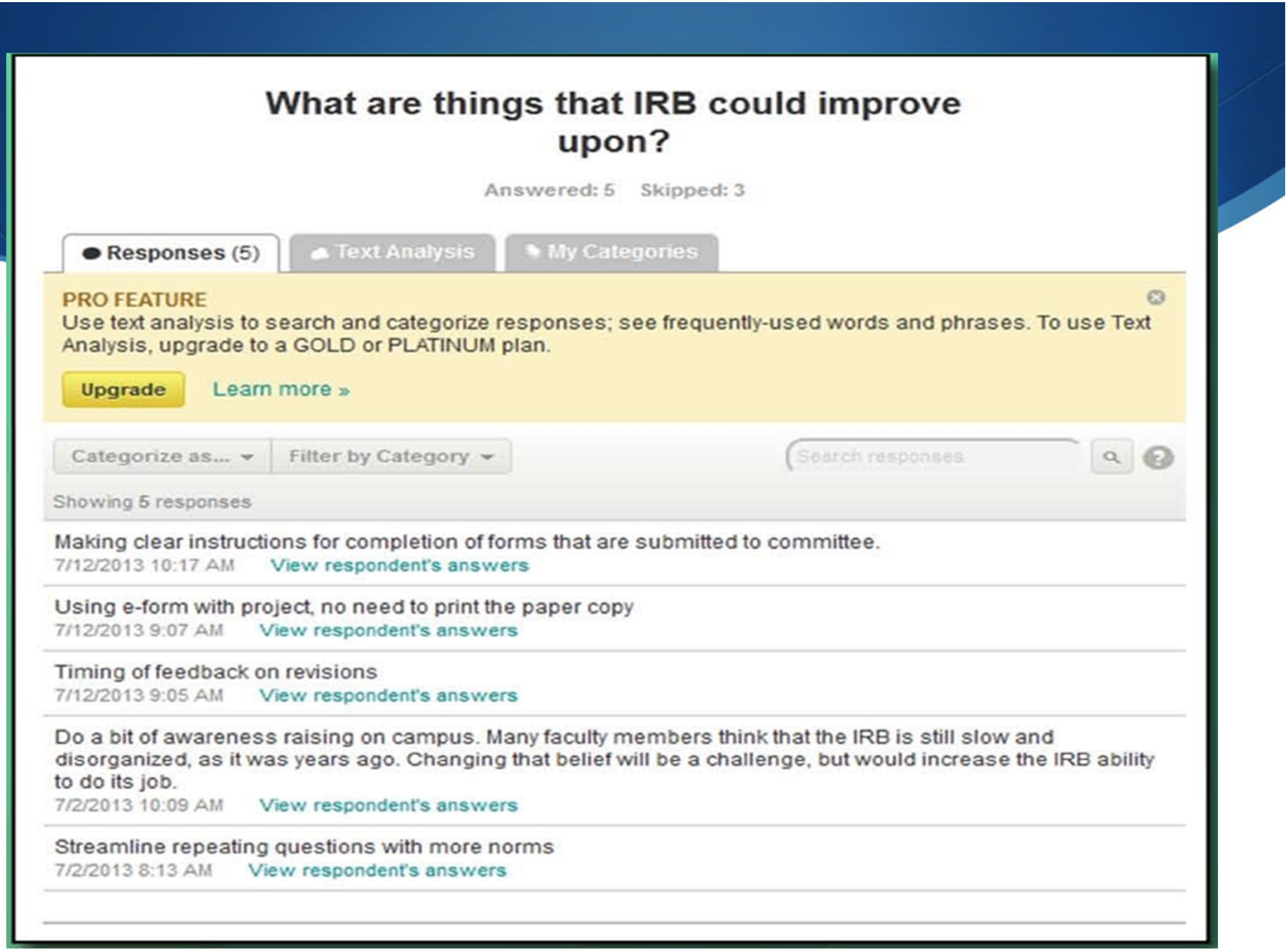
The communication is very well, keep us on-track. The committee members treat each other with respect, nice teamwork, well organized
7/12/2013 9:07 AM View respondent's answers

I think the site is simple and easy to find the information we need
7/8/2013 1:42 PM View respondent's answers

Management of IRB submissions and review process. Much more reliable and streamlined.
7/2/2013 10:09 AM View respondent's answers

distribution of labor use of paperless system manner in which meetings are conducted communication outside of meetings
7/2/2013 9:30 AM View respondent's answers

Clearly and effectively analyze all protocols with a main objective to safeguard those researchers
7/2/2013 8:13 AM View respondent's answers


What are things that IRB could improve upon?
Answered: 5 Skipped: 3
Responses (5)
Text Analysis
My Categories
PRO FEATURE
Use text analysis to search and categorize responses; see frequently-used words and phrases. To use Text Analysis, upgrade to a GOLD or PLATINUM plan.
Upgrade
Learn more »
Categorize as...
Filter by Category
Search responses
Showing 5 responses
Making clear instructions for completion of forms that are submitted to committee.
7/12/2013 10:17 AM View respondent's answers
Using e-form with project, no need to print the paper copy
7/12/2013 9:07 AM View respondent's answers
Timing of feedback on revisions
7/12/2013 9:05 AM View respondent's answers
Do a bit of awareness raising on campus. Many faculty members think that the IRB is still slow and disorganized, as it was years ago. Changing that belief will be a challenge, but would increase the IRB ability to do its job.
7/2/2013 10:09 AM View respondent's answers
Streamline repeating questions with more norms
7/2/2013 8:13 AM View respondent's answers

Embedding Ethics Into Brief Training Videos

Jwo cp#Jwdlgevu#

Cecfgo ke#Rqrke{#323

Cecfgo ke#Rqrke{#423

Cecfgo ke#Rqrke{#523

The free time that is gained by using a brief, series of videos is dedicated to building campus awareness and culture including:

- visiting classes & clubs
- attending faculty committee meetings
- connecting with major research stakeholders
- board meetings

Sample of Ethical Principles:
Minimize risks
Risk benefit ratio
Equitable selection
Consent
Data monitoring
Privacy/confidentiality
Vulnerable populations

Sample Federal Agencies:
USDHHS, FDA,
USDA, NIH, OLAW

Sample of Reviews:
Human Subjects
IACUC
Amendments
Renewals

Monitoring Activities:
OHP
Inspections & Audits

Sample Training:
RCR
IRB
IACUC

Noncompliance:
Fabrication
Falsification
Plagiarism

Staff Roles and Professional Orgs:
Institutional Official
Director
Committee Chair & members
Staff
SRA, PRIM&R, NGMA, NCURA, AAALAC

Cooper, J.A. (2011). Institutional Review Board (IRB) 201: An In-Depth Analysis of the Criteria for Review. Public Responsibility in Medicine and Research. Boston, MA.

When Times Change

Scholarly Activity Strategic Positioning Platform

Mission

Research, scholarship and creative projects are one of the three strategies (teaching, service, and scholarship) that UCM uses to ensure top notch faculty will engage their students in relevant co-curricular experiences that exemplify learning to a greater degree.

Positioning Statement

Research, scholarship and creative projects are a pragmatic approach to attaining knowledge:

- keeping both faculty and students current with hands-on experience in discipline-specific techniques;
- shaping the future through greater degrees of skill development, collaboration and problem solving;
- producing knowledge and further inquiries which positively impact local communities and the world.

Human Subjects Research
Stakeholders and Vulnerable Groups

Research Pool

Research Subjects

Researchers

IRB Members

IRB Administrators

Institutional Administrators

Funders

Current Students

Future Students

Current Faculty

Future Faculty

Current Employees

Future Employees

Community

Taxpayers

FSGO Elements of an Effective Compliance Program

Designation of a Compliance Officer
Development of Compliance Policies
Development of Open Lines of Communication
Provision of Training and Education
Internal Monitoring and Auditing
Response to Detected Deficiencies
Enforcement of Disciplinary Standards
Assessment of Program's Effectiveness

Combatting Resistance to Process Improvements

Ability to demonstrate compliance with regulations

Stability and equality/fairness (and bureaucracy, which is not always bad)

Ground rules and performance expectations

Lessens waste

Helps identify and locate “other” problems

Appropriate Intervention Ladders

Guide choices through incentives;

Guide choice through disincentives;

Restrict choice;

Eliminate choice.

Questions?

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