

# HRPP/IRBs Update

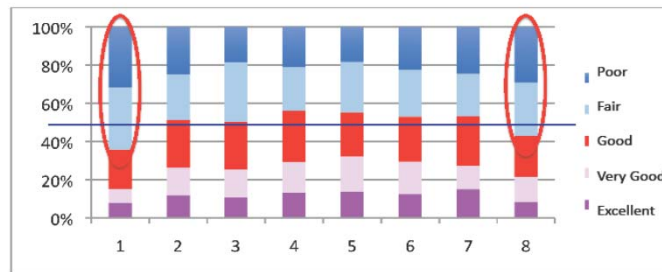
Human Research Protection Program (HRPP)  
accredited by the  
Association for Accreditation of Human Research Protection Programs  
(AAHRPP) since June 2015

Presented by:  
Catherine L. Higgins, Ph.D., CIP, CIM  
HRPP Director



2015 CPI Survey: Compliance Ratings

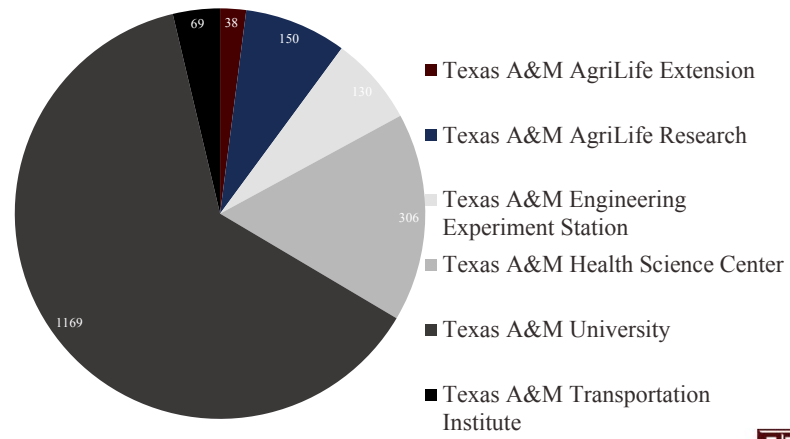
## Q71: Human Subjects Research Ratings



- 1 – Turnaround (1<sup>st</sup>)
- 2 – Turnaround (amend)
- 3 – Timely interactions
- 4 – Customer service (staff)
- 5 – Knowledge (staff)
- 6 – Clarity of revision
- 7 – Turnaround (proto)
- 8 – Timely negotiation



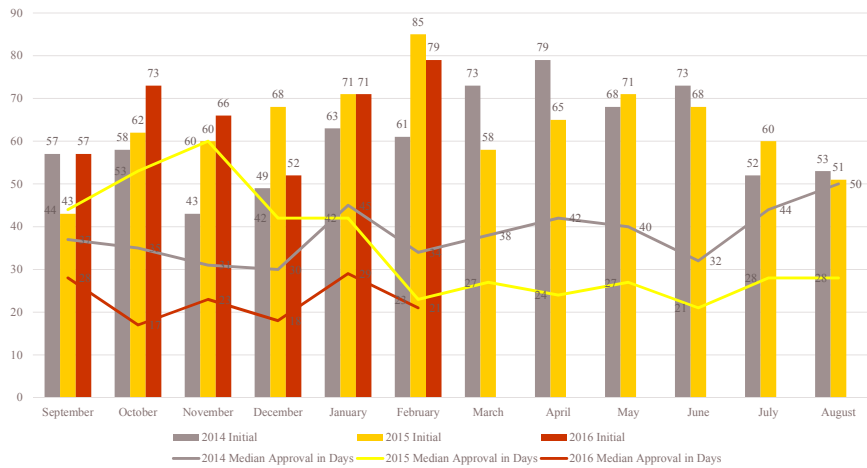
# HRPP/IRB Active Protocols by Institution FY15



**Total:  
1862**

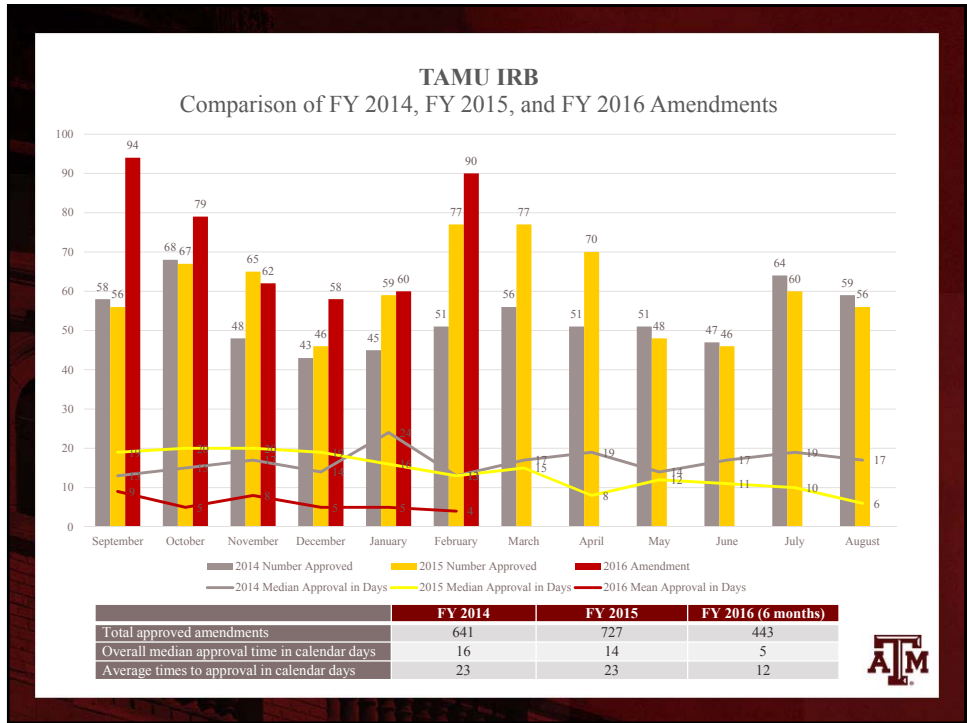


## TAMU IRB Comparison of FY 2014, FY 2015 and FY2016 New applications



	FY 2014	FY 2015	FY 2016 (6 months)
Total approved new applications	729	762	397
Overall median approval time in calendar days	38	37	23
Average times to approval in calendar days	44	51	34





- ## Intrasystem Agreements
- TAMU IRB reviews for:
    - Texas A&M University
      - Galveston
      - Qatar
    - Texas A&M University Health Science Center
    - Texas A&M Transportation Institute
    - Texas A&M AgriLife Extension Service
    - Texas A&M AgriLife Research
    - Texas A&M Engineering Experiment Station
    - Texas A&M Engineering Extension Service\*
  - BCD IRB reviews only BCD studies.

# Human Research Protection Program

## Key Personnel:

- Institutional Review Board (TAMU IRB)
  - Dr. James Fluckey, Chair
  - Dr. David Martin, Vice Chair
- Institutional Review Board (BCD IRB)
  - Dr. Emet Schneiderman, Chair
  - Dr. Diane Flint, Vice Chair
- Human Research Protection Program Director
  - Dr. Catherine Higgins



# IRB Composition Requirements

- The requirements for IRB membership are addressed in the HHS regulations at [45 CFR 46.107](#)
- An IRB must:
  - have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
  - make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
  - include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
  - include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
  - not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Please see the regulations at [45 CFR 46.107](#) for complete information on all of the required qualifications to properly compose an IRB.



## Contacts

### HRPP Director

Catherine L. Higgins, Ph.D.,  
CIP, CIM  
[clhiggins@tamu.edu](mailto:clhiggins@tamu.edu)

979.458.4117

Adjunct Associate Professor,  
Department of Health Policy  
and Management, School of  
Public Health

### Post Approval Monitors

Kory Douglas, Ph.D.

[kodouglas@tamu.edu](mailto:kodouglas@tamu.edu)

979.458.5532

Vacant position

### TAMU IRB Liaisons

Amy Donnellan, M.A.

[adonnellan@tamu.edu](mailto:adonnellan@tamu.edu)

979.862.3653

Aline Lovings, M.A., CIP

[alovings@tamu.edu](mailto:alovings@tamu.edu)

979.862.4682

Denise Puga, Ph.D.

[denisepuga@tamu.edu](mailto:denisepuga@tamu.edu)

979.458.5590

Jennifer Rau-Hug, MJHL

[jenniferhug@tamu.edu](mailto:jenniferhug@tamu.edu)

979.865.7037

Graeme Wright, M.S.

[graemewright@tamu.edu](mailto:graemewright@tamu.edu)

979.862-4681

### iRIS Support Team

[outreachrcb@tamu.edu](mailto:outreachrcb@tamu.edu)

979.845.4969



## Accomplishments

- Successfully completed the AAHRPP accreditation process.
- Simplified training requirements by reducing the frequency of refresher training from every 3 years to every 5 years.
- Reviewed and updated all standard operating procedures to meet AAHRPP accreditation standards and streamlined procedures for the TAMU and BCD IRBs so that each IRB follows the same standard operating procedures to the extent appropriate.
- To meet AAHRPP requirements, developed contract negotiation tools and templates for SRS to utilize in negotiating projects involving human research.
- Expanded training and outreach programs.
- Developed and implemented University SAP on Institutional Conflict of Interest in Human Research to meet AAHRPP requirements.

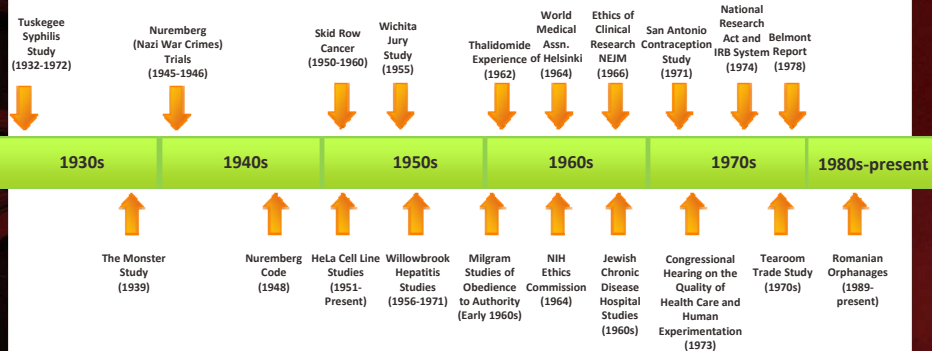


# Moving Forward

- Complete enhancements and updates to the IRB applications to ease administrative and researcher burdens
- Respond to significant regulatory changes (e.g. update processes and procedures, outreach and education, etc.)
- Continue to review processes and procedures for opportunities to enhance efficiencies and effectiveness and ease administrative burdens on researchers



## Historical Ethical Atrocities



### Resulting Key Concepts

- |                                 |                                 |
|---------------------------------|---------------------------------|
| Voluntary consent               | Qualified investigators         |
| Freedom from coercion           | Appropriate research design     |
| Comprehension of risks/benefits | Freedom of subjects to withdraw |
| Minimization of risk and harm   | Favorable risk/benefit ratio    |



## Basic Ethical Principles

- Respect for Persons
  - autonomy of subject
- Beneficence
  - benefits outweigh risks
- Justice
  - selection of subjects is equitable



## Where We Are Today

- Federal Regulations
  - “The Common Rule” – June 18, 1991
  - 45 CFR 46 – Basic Department of Health and Human Services Policy for Protections of Human Research Subjects
    - Definitions of Research and of Human Subjects
    - Criteria for review of Human Subjects Research
  - Food and Drug Administration
  - ANPRM, NPRM – OHRP, AAHRPP



# Additional Regulations

- Special considerations for research funded or regulated by:
  - Agency for International Development
  - Department of Agriculture
  - Department of Commerce
  - Consumer Product Safety Commission
  - Department of Defense
  - Department of Education
  - Department of Energy
  - Environmental Protection Agency
  - Department of Health and Human Services
  - Department of Housing and Urban Development
  - Department of Justice
  - National Aeronautics and Space Administration
  - National Science Foundation
  - Department of Transportation
  - Department of Veterans Affairs
  - Central Intelligence Agency\*
  - Department of Homeland Security\*
  - Social Security Administration\*



\* Denotes compliance with ALL subparts of 45 CFR part 46, but have not issued the Common Rule in regulations



# Is it Research?

- The federal regulations define research as:
  - “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(d)).
- As described in the Belmont Report:
  - “...the term ‘research’ designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”
  - Data must be generated and analysis of the data should occur.





## Is It a Human Subject?

- A human subject is defined by Federal Regulations as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 CFR 46.102(f)(1),(2))
  - Intervention includes physical/psychological procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.



## Where We Are Today

- Institutional Role
  - Institutions that “engage” in human subjects research conducted or supported by HHS must sign a written assurance committing them to compliance with HHS regulations.
  - University Rule
  - Research conducted (1) by or using Texas A&M faculty, staff, and/or students and/or (2) on Texas A&M property must be reviewed by the TAMU IRB.
  - Check the box
  - TAMU HRPP involves all human subjects research.
    - Exempt also
  - We work collaboratively with other IRBs



## Conflicts of Interest – Financial and Non-financial

- Key Study Personnel
- External Study Personnel
- IRB Member/Consultant
- Institutional



## Interactions with SRS

- Notifications
  - PI Compliance Statement
  - Proposals
  - Awards
  - Subawards
- Modified IRB approval
- Contact me directly if funding issue



## Student Research

- OGAPS
- Undergraduate - LAUNCH
- Bush School
- EdD



## Multisite Research

- Work collaboratively with other IRBs and institutions
- Accept applications from other IRBs
- Considerations
  - External personnel
  - Scott & White
  - Qatar
  - International



## Training for Study Personnel

- Required by regulations
- CITI Training
  - Must be renewed every five years
  - Web-based ethics course
  - All study personnel must complete CITI training with a minimum score of 90 percent.
  - [www.citiprogram.org](http://www.citiprogram.org)
  - More information available at: <http://rcb.tamu.edu/humansubjects/training>
- Alternative Training
  - Possible for special circumstances
  - Guidance available on the website: <http://vpr.tamu.edu/compliance/rcc/irb/irb-guidance/Alternativetrainingforspecialcircumstances.pdf>



## Submission Process for Research with Human Subjects

Submit Required Documentation

Pre-review

Review by Committee

Communicate Outcome

Conduct Research

★ Can include requests for revisions



## Why?: The Submission Process

- Purpose: To gain approval to conduct research involving human subjects
- Goal: To protect the rights and welfare of research subjects
- Perspective: From the viewpoint of the human subject



## How to Submit Your Project

- Online system – iRIS
  - <http://imedris.tamu.edu>
- Information
  - Help line (979.845.4969)
  - HELP button
  - FAQs on the website:  
<http://rcb.tamu.edu/humansubjects/faqhumansubjects>



## IRB Application

- iRIS application includes branching
- Different for social/behavioral versus biomedical
- Exempt has fewer questions than expedited and full board applications
- Changing order of application to shorten exempt
- Consistency – the application includes a question about related IRB studies
- N/A is appropriate if question does not apply
- Compensation is not a benefit



## Liaison Assignments

- **Amy Donnellan**
  - Texas A&M AgriLife Research
  - College of Agriculture and Life Sciences
  - College of Education & Human Development – TLAC
  - College of Veterinary Medicine & Biomedical Sciences
  - Texas A&M AgriLife Extension Service
- **Aline Lovings**
  - College of Education & Human Development – HLKN
  - College of Engineering
  - Texas A&M Engineering Experiment Station
  - Texas A&M Engineering Extension Service
  - Texas A&M Transportation Institute
  - Texas A&M – Qatar
- **Denise Puga**
  - College of Education & Human Development – EAHR
  - College of Education & Human Development – EPSY
  - College of Liberal Arts – Psychology
- **Jennifer Rau-Hug**
  - Bush School Of Government and Public Service
  - College of Geosciences
  - College of Science
  - Mays Business School
  - Texas A&M Health Science Center
- **Graeme Wright**
  - Baylor College of Dentistry
  - College of Architecture
  - College of Liberal Arts - (except Psychology)
  - School of Law
  - Texas A&M - Galveston



## Pre-Review

- Review before the IRB
- Consistency
- Logistics
- Timeline
- Compliance



## Eight Ethical Assessment Criteria

- Risks are minimized
- Risks are reasonable vs. benefits
- Selection is equitable
- Informed Consent is obtained
- Participation is voluntary
- Data and Safety are protected/monitored
- Privacy and confidentiality are upheld
- Vulnerable population protections are enhanced

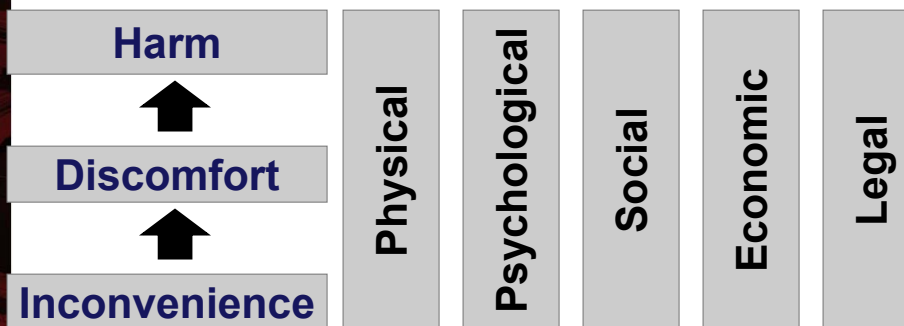


## Scientific Review

- Regulations require scientific review
- Sign off (department head/supervisor)



## Types of Risks





## Categories of IRB Review

### EXEMPT

- No/minimal risk
- Existing data
- 5-year continuation
- IRB Chair/HRPP staff

### EXPEDITED

- Minimal risk
- Prospective data
- Annual continuing review
- Single IRB member
- Identifiers

### FULL BOARD

- Greater than minimal risk
- Annual continuing review
- Review by two IRB members then IRB



## How Is the Category Determined?

- The IRB chair or designated reviewer will make the regulatory determination.
- The project methodology and administration can play a role in determining the category.
  - Choices can raise/lower risk to subjects



# Vulnerable Populations

- Additional safeguards must be implemented for populations in which research may pose additional and/or unknown risks.
- For example
  - Pregnant Women, Human Fetuses, and Neonates
  - Prisoners
  - Children
  - Economically disadvantaged
  - Socially disadvantaged
  - Educationally disadvantaged
  - Cognitively impaired
  - Disabled
  - Students



# Criteria For Exempt Research

- Research conducted in established educational settings
- Use of educational tests, surveys, observation unless:
  - Information is recorded so that subjects can be identified
  - Responses could place the subjects at risk of liability or be damaging
- Use of educational tests that is not exempt if:
  - Subjects are public officials or candidates for office
  - Federal statutes require confidentiality be maintained throughout the research and thereafter



## Criteria For Exempt Research

- Research involving collection of existing data if these sources are publicly available or de-identified
- Research and demonstration projects, conducted by the approval of department or agency heads, which are designed to examine:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services
  - Possible changes to those programs
  - Possible changes in methods of payments for benefits or services
  - Project must be conducted pursuant to specific federal statutory authority
  - Must be no statutory requirement that the project is reviewed by an IRB
  - Must not involve significant physical invasions upon the privacy of participants
  - The exemptions should have authorization of concurrence by the funding agency
- Taste and food quality evaluation studies



## Criteria for Expedited Review

- Clinical studies of drugs and medical devices for which IND or IDE applications are not required
- Collection of blood samples (with specific parameters)
- Prospective collections of biological specimens for research purposes by noninvasive means
- Collection of data through noninvasive procedures routinely employed in clinical practice (excluding X-ray and microwave)
- Materials collected or to be collected solely for non-research purposes



## Criteria for Expedited Review

- Collection of data recordings (voice, digital, etc.)
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.



## Full Board Operations

- Meetings first Wednesday of the month
- Protocols must be through pre-review two Mondays prior to meeting
- Meetings are closed but PI or study personnel should be available
  - Phone
  - In-person
- Communicate outcome by Friday after meeting typically



## Possible Outcomes

- Additional Revisions
  - Reviewers may request additional revisions.
  - Revisions may breed the need for more revisions or clarification.
- Review Status
  - The review status is available in submission tracking in iRIS. Your liaison rarely knows more about the review status than iRIS knows.
  - Reviewers are allowed at least two weeks to review.
  - Deferred – may be revised and resubmitted
  - Pending – will be approved when specific confirmations are complete
  - Disapproved – only done by IRB or IO
  - Approved – only done by IRB, IRB Chair, or designee
  - Exempt determination
- Approval – can begin human research



## Am I Done?

- Not quite!
  - Keep HRPP informed and study documents current
    - Submit any desired project changes as Amendments
    - Submit any new documents (such as grant approval) or provisions
    - Yearly Continuing Review for Expedited and Full Board projects (exempt – five years)
    - Report any adverse events or deviations
    - Submit a completion report when all study procedures **and** data analysis are complete



## Post Approval Monitoring

- PI Self-Assessment  
[http://cb.tamu.edu/humansubjects/resources/pi\\_selfassessment\\_humansubjectsresearch](http://cb.tamu.edu/humansubjects/resources/pi_selfassessment_humansubjectsresearch)
- Pre-initiation meeting
- Maintain study documents
- Readily available upon request
- Prepare for potential audits by sponsor
- Anticipate each study being monitored every three years
- Maintain compliance
- Educational process
- Assist in responsible conduct of research



## Red Flags List

- human samples, cells, tissues;
- research on education instructional strategies;
- research on involving normal educational practices;
- research involving educational tests, surveys, interviews, observation of public behavior;
- research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;
- research and demonstration projects designed to study, evaluate, examine public benefit or service programs;
- taste and food quality evaluation;
- consumer acceptance studies;
- research on drugs;
- research on medical devices;
- collection of blood samples;
- collection of biological specimens;
- collection of data routinely employed in clinical practice;

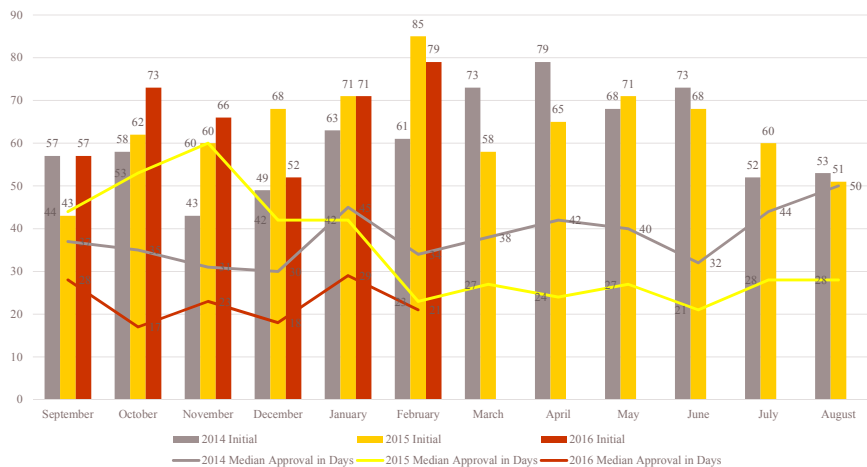


## Red Flags List (continued)

- x-ray;
- microwave;
- collection of data from voice, video, digital, or image recordings made for research purposes;
- research on individual or group characteristics or behavior;
- research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior;
- survey;
- interview;
- oral history;
- focus group;
- program evaluation;
- human factors evaluation;
- quality assurance methodologies



**TAMU IRB**  
Comparison of FY 2014, FY 2015 and FY2016 New applications



	FY 2014	FY 2015	FY 2016 (6 months)
Total approved new applications	729	762	397
Overall median approval time in calendar days	38	37	23
Average times to approval in calendar days	44	51	34



# Questions?

## Human Subjects in Research

- Website:
  - <http://rcb.tamu.edu/humansubjects>
- Phone:
  - 979.458.4067

