WKU Office of Research & Creative Activity

ALL THINGS RESEARCH COMPLIANCE WORKSHOP

September 09, 2025

Presented by: The Office of Research Integrity & Procurement Services

AGENDA

- Responsible Conduct of Research (RCR) Continuing Education Training
- Review RCR case studies in breakout groups followed by discussion with the whole group.
- Break (10 minutes)
- Overview of The Office of Research Integrity services
- Other considerations/ Questions?
- Break (10 minutes)
- Overview of Procurement Services related to Compliance
- Thank you for attending!

Responsible Conduct of Research (RCR) Continuing Education

- Why is Responsible Conduct of Research (RCR) Continuing Education important?
- Develop, foster, and maintain a culture of integrity in science;
- discourage and prevent unethical conduct;
- empower researchers to hold themselves and others accountable to high ethical standards;
- increase knowledge of, and sensitivity to, ethical issues surrounding the conduct of research by researchers with diverse backgrounds;

https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training

Responsible Conduct of Research (RCR) Continuing Education Cont.

- improve the ability to make responsible choices when faced with ethical dilemmas involving research;
- provide an appreciation for the range of accepted scientific practices for conducting research;
- inform scientists and research trainees about the regulations, policies, statutes, and guidelines that govern the conduct of U.S. Public Health Service-funded research and promote compliance with the same; and,
- promote a career-long positive attitude toward research ethics and the responsible conduct of research.

https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training

History of Research Abuses

Slide provided by CIRTification

Historical Perspectives

- There are many examples throughout history of research causing harm:
- Exploiting disadvantaged populations without benefit
- Experimenting on people without their knowledge
- Dangerous research
- Violations of privacy

Slide provided by CIRTification

Milgram Obedience Studies (1960s)

- Stanley Milgram, social psychologist
- Wanted to see how far “obedience” would go
- Did not reveal whole truth about the experiment
- Participants told to give electric shocks to an unseen individualin another room
- Shocks were not real, but many people did not stop despite protests
- Caused anxiety, embarrassment, and discomfort for participants
- Not enough debriefing

Slide provided by CIRTification

Havasupai Tribe (1990s)

- Live in Grand Canyon in Arizona
- Researcher from University of Arizona collected blood samples from tribe members to study type II diabetes
- Researcher also used samples to study schizophrenia
- Shared samples with other researchers
- Tribal leaders would not have agreed to this
- No information from diabetes study shared
- Privacy violations

Public Health Service Study of Untreated Syphilis in the Negro Male (Tuskegee)

- Government-funded
- Macon County, Alabama, 1932-1972
- What happened when syphilis left untreated?
- increased disability and early death – already known!
- Recruited black men only
- Men tested for syphilis but not told they had it
- Infected men kept from getting treatment even though treatment (and later cure) available

Slide provided by CIRTification

Public Outrage Over Tuskegee

- Many scientists knew about the Tuskegee syphilis study – it was NOT a secret!
- But once it was reported in Washington, DC newspaper, the public demanded government action
- A federal commission was formed to address protection of research participants and develop federal guidelines

Slide provided by CIRTification

Take Home Message

- Public outrage over research abuses led to increased government involvement and regulations for research.

Slide provided by CIRTification

Team up into groups of 4 people

- Each group will be assigned a case study to review.
- Please carefully read the case study and respond to the accompanying questions.
- After the group discussion, we will reconvene as a whole group to discuss each case study and share insights.

Case Study Groups

- **20 minutes in breakout session to read and answer questions regarding your groups case study.**

- **Bring back to full group to discuss each case study together.**

Case One: Putting Social Advocacy Before the Data

Discussion Questions

- What are the factors that you think motivate some scientists to become advocates?
- How should Helen address this issue with her students?
- Is there an ethical difference between falsifying data to support a socially important conclusion and suppressing the publication of data that do not support the same conclusion?
- Is it ever acceptable to suppress the publication of scientifically valid data for social reasons?
- Should scientists ever engage in social activism using their data? Or does science require one to remain objective and engage all sides of a debated issue?

Case Two: Career Dreams Up in Smoke?

Discussion Questions

- Does Brett have an ethical obligation to refuse the job? To take the job?
- How should Brett reconcile the needs of his family versus the needs of society? Does he owe a greater obligation to care for his family?
- Is neuroscience research aimed at stimulating subconscious thoughts or behaviors ethical? Is it regulated by anyone?
- Have you ever watched a commercial and felt that you have been manipulated to buy something, or drink something? Did that make you feel as though your rights had somehow been violated?

So, who needs Responsible Conduct of Research (RCR) Training

1. WKU has contracted with a third party, Collaborative Institutional Training Initiative (CITI) to provide online training for RCR. The RCR program through CITI is a required training for all students, trainees, faculty and staff that are involved in research at WKU (funded or unfunded)

To successfully complete RCR CITI training. WKU requires that each training module must be passed with a minimum score of 80%.

2. Continuing education and ongoing training including but not limited to, face-to-face instruction, reading assignments, etc., identified and tracked by each Principal Investigator. The NIH recommends eight hours of continued instruction/training and requires face-to-face discussions.


TIME FOR A
BREAK

The Office of Research Integrity

- The Office of Research Integrity (ORI) provides guidance to protect the rights, welfare, and security of individuals involved in research activities at WKU and its surrounding communities, ensuring compliance with federal, state, and local regulations.

- Committed to maintaining the highest standards, ORI ensures all research at WKU adheres to institutional policies and oversight requirements mandated by federal and state laws. Non-compliance may result in significant penalties for both WKU and individual researchers. WKU is dedicated to fostering a culture of compliance and promoting responsible research conduct.

Services Provided

For inquiries regarding compliance and research integrity, contact the Office of Research Integrity.

CITI Trainings	IRB: Human Subjects	FCOI
IACUC	Export Controls	IBC: Institutional Biosafety Committee

The Institutional Review Board (IRB) oversees Human Subjects Research

- Human research is regulated by federal guidelines.
- These rules and regulations are necessary because research has the potential to harm participants (intentionally or unintentionally).
- These rules and regulations were created based on three key ethical principles:

1. Respect for autonomy: All people should be allowed to make their own decisions. Research participants should have enough information to decide if they want to take part in a research study.

2. Beneficence: Researchers must protect participants from harm and try to provide benefits when possible. (risk vs. benefit)

3. Justice: Certain people or groups should not be targeted, used for or excluded from research for convenience. The risks and benefits of research should be shared equally across all groups of people.

WKU Institutional Review Board (IRB) reviews research protocols to make sure that the rules for research are followed. A research project must be reviewed and approved by an IRB before it can start.

- Researchers must explain to the IRB:
  - a. What risks there might be and how participants will be protected
  - b. How participants will be identified and invited to take part in research
  - c. What participants will be told about the study and how consent will be documented
  - d. How information collected about research participants will be kept safe

- Researcher responsibilities also include:
  - a. Conducting research according to IRB policies
  - b. Contacting and signing up participants using approved materials and processes
  - c. Obtaining informed consent from participants prior to participation
  - d. Submitting information about ongoing studies to the IRB for continuing review
  - e. Reporting adverse or unanticipated events
  - f. Submitting any changes (amendments) for IRB approval

IRBNet.org

This is for training ONLY (considered a training/sandbox account

IRBNet Information

IRBNet.org

"New Registration" Training

"Researcher 1: New Project Submission" Training

"Researcher 2: Post-Submission Advanced Topics" Training

For three further training sessions within IRBNet, use the following respective Usernames with Password:

Usernames: wkuresearch1; wkuresearch2; and wkuresearch3
Password: training

For reference, the training site is a mirror image of our live site for practicing with IRBNet tools and functions.

For project review, submit through the Live Site @ (https://irbnet.org/).

***Note: If the submission says 'work in progress' that means it is not fully submitted. Please make sure you have selected 'submit this package' (under project administration) on the left-hand side of the screen and follow the prompts. The project should say 'pending review' when it is fully submitted to the live site.

The Institutional Review Board (IRB) Tentative meeting dates and co-chairs

- Meetings will be held via ZOOM on a monthly basis
- All meetings will be tentatively scheduled to begin at 10:15 am.
- Schedule changes may occur.
- APPLICATIONS NEED TO BE TURNED IN BY THE FIRST OF THE MONTH TO BE REVIEWED AT THAT MONTH'S MEETING. For example: If you have an application turned in by February 1- The Full Board review will be in February. If you turn in an application February 8- The Full Board review will be in March.

Dr. Leslie North, Department Chair – EEAS and Dr. Dana Sullivan, Professor, Social Work are the IRB Co-Chairs

Other Considerations

1. I am collecting data for an evaluation; do I need IRB approval?
2. I am collecting data, but I consider this data oral history, do I need IRB approval?
3. I am ONLY working with a pre-existing data set. Do I need to go through any sort of IRB process?
4. Do I need to gain IRB approval for a classroom project?

Payments to Foreign Nationals

- There are special tax considerations and paperwork
- If you are paying foreign individuals or entities, they may be subject to up to 30% in taxes
- Each situation is different as the tax treatment takes into consideration things such as VISA type, type of income, & whether there is a tax treaty with their tax home country to name a few.
- There are some things that are not allowed depending on VISA types.

Please feel free to contact me with any questions

Nicole Boaz, Tax Compliance Accountant
270-745-5859
nicole.boaz@wku.edu

Institutional Animal Care and Use Committee (IACUC)

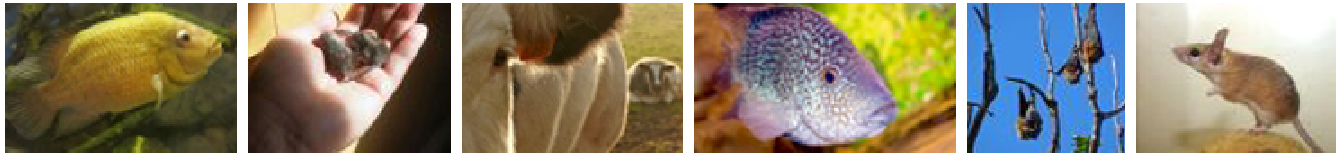
Research Integrity ORCA Sponsored Programs GCA News Staff Contact Us

- Application (doc)
- Continuing Review (doc)
- Links
- WKU IACUC Policy

Meetings and laboratory inspections occur on a semi-annual basis unless ad-hoc meetings are needed.

Animal Care and Use

The use of animals for instructional, demonstration or research purposes comes under the federal guidelines of the Office of Laboratory Animal Welfare and the U.S. Dept. of Agriculture. All animal use in such projects must receive prior approval from the Institutional Animal Care and Use Committee (IACUC). Questions may be directed to Dr. Phillip Gunter, Assistant Professor - Agriculture & Food Science, tel. (270) 745-3151.



IACUC Procedures

Western Kentucky University has an Assurance of Compliance with Public Health Service Policy of Humane Care and Use of Laboratory Animals

Western Kentucky University, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

1. Full Committee Review - Under full committee review, a quorum of the committee must meet in person (audio/video conferencing has been allowed in special situations) to discuss the proposal. After discussion, a vote on approval is taken and a majority of members must vote to approve. Dissenting members can submit a "minority opinion" in the meeting minutes if they wish.
2. Designated reviewer method - The proposals are sent to the committee and everyone is allowed one week to submit a request that the proposal be reviewed using the "full committee review" method. If no one requests a full committee review, the chair can assign the proposal to one or more members for review. The designated reviewer(s) can approve the proposal, grant approval upon minor changes, or request a full committee review. The designated reviewer(s) cannot deny approval. Only the full committee, in a convened meeting, can deny a proposal.

Institutional Biosafety Committee (IBC)

Research Integrity ORCA Sponsored Programs GCA News Staff Contact Us

- IBC Application
- IBC Documents
- IBC Links
- IBC Members
- IBC Policies and Bylaws
- University Research Policy

Institutional Biosafety Committee

Scope of the Committee

Western Kentucky University's Institutional Biosafety Committee (IBC) is a federally mandated review committee which oversees all research involving recombinant deoxyribonucleic acid (rDNA) molecules and the use of microorganisms for biological research. The IBC provides documentation that all WKU faculty, staff, and students who work with rDNA and/or microbes have passed the laboratory safety course offered by the WKU Department of Biology. All documents will need to be turned in to the Office of Research Integrity, ori@wku.edu, for review and approval.

Meetings and laboratory inspections occur on an annual basis unless ad-hoc meetings are needed.

Dr. Rodney King, Professor, Biology, is the IBC Chair

Export Controls

- It is the policy of Western Kentucky University (WKU) to comply fully with the U.S. export control laws and regulations.
- Export control laws restrict certain types of information, technologies, and commodities that can be transmitted overseas to individuals, including U.S. citizens, or made available to foreign nationals on U.S. soil. It is also the mission and policy of WKU to conduct services openly and without exclusions on the publication and dissemination of academic and research activities. It is the responsibility of administrators, faculty, staff, students, and collaborators to be aware of and comply with these laws and WKU's written procedures.

Export Controls Pre-Approval Checklist
For Office of Research Integrity / Compliance Review

1. Project & Personnel

- PI, title, funding source, foreign nationals involved
- Location of work (domestic/foreign)

2. Controlled Technology / Data

- Involves ITAR, EAR, or OFAC-controlled items?
- Use of encryption, sensitive data, or restricted software?

3. International Involvement

- Foreign collaborators or travel?
- Shipping or hand-carrying materials abroad?

4. Equipment / Materials

- Export-controlled equipment or biologicals?
- Technology Control Plan (TCP) needed?

5. Data Security & Restrictions

- Access restrictions or publication limitations?
- Remote access or cloud storage involved?

6. Compliance Actions

- Sanctions screening (OFAC, Entity List, DPL)
- License required? Applied? Approved?

7. Training & Approval

- PI & personnel completed export control training
- Final compliance review & approval required before project starts

Collaborative Institutional Training Initiative (CITI) Trainings

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CITI Research Trainings

The Office of Research Integrity has put together a series of trainings through CITI that will help WKU Faculty and Staff meet federal, state and local requirements. All trainings will be geared for Human Subjects (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Export Controls, and Financial Conflict of Interest (FCOI).

CITI is a web-based ethics training course for those conducting research. All who utilize CITI for compliance training, including Principal Investigators, Co-Investigators, and Faculty Sponsors, must complete CITI training with a minimum score of 80%. The compliance manager will verify completion records of study personnel, and these should be maintained by the Principal Investigator and are subject to periodic inspection by the committees.

Follow these directions to set up a CITI account:

- Go to www.citiprogram.org
- Select "Register" in upper right corner
- Step 1 - Select your organization affiliation: Western Kentucky University, and agree to terms of service
- Step 2 - Enter your name and email
- Step 3 - Create your Username and Password
- Step 4 - Finish registration by answering organization-specific questions
- Check the course(s) you are required to complete - Note that the first course required is "Social and Behavioral Responsible Conduct of Research" aka RCR

Training Briefs for CITI:

- CITI Guide to Getting Started
- CITI Program offered Trainings

Research Security Training Requirement

- This mandate stems from a growing awareness of the threats to the integrity of the U.S. research enterprise.
- The primary driver is safeguarding federally funded research from misappropriation, violations of research integrity, and interference by foreign governments. The U.S. government has expressed concerns about certain foreign entities exploiting the openness of U.S. research environments, including universities, to acquire sensitive information, technology, and intellectual property.
- CHIPS and Science Act of 2022: This act further codified the requirement for research security training, among other provisions.
- MFTRP disclosures

Research Security (CITI) Training

- Based on current federal agency requirements for research security training, here's a list for when training dates are due for external funding:

1. Department of Energy (DOE): For applications submitted on or after May 1, 2025, covered individuals must certify they've completed research security training within the 12 months immediately preceding the application date.
2. National Institutes of Health (NIH): Effective October 1, 2025, NIH recipients must provide training to all faculty and researchers identified as Senior/Key Personnel on the requirement to disclose all research activities and affiliations (active and pending)
3. National Science Foundation (NSF): Effective October 10, 2025, NSF will require completion of research security training within 12 months prior to proposal submission.

- While the DOE, NIH, and NSF have established timelines, other federal agencies are expected to implement similar requirements in the near future.

Research Security (CITI) Training Cont.

The training is very similar to RCR training with a focus on foreign collaborations/elements.

Here is some information on how to ensure you connect to correct module in CITI, but if you have any specific questions, please reach out to ORI@wku.edu.

- **If the "Research Security Training (Combined)" training module does not show up on your active or ready to begin course list, you can select "Add a Course" at the bottom of the page.**
- **On the select curriculum page, click "No" and then "Next". A full list of WKU course offerings should be listed. Select "I want to complete or I am required to complete a Research Security training course." and "Next".**
- **Select the course titled "Research Security Training (Combined Course) A condensed and combined single-module course based on the NSF's Research Security Training." and "Next" to add it to your available courses.**
- **Click "Start Now" to begin the course. A PDF certificate of completion will be available once you have completed the course.**

Research Security (CITI) Training

(if required by a federal sponsor)

- From Pre-award: Notification will be made via the following methods:

1. Noted on the PIF intake form
2. Noted in the PIF email response
3. Noted on the checklist with an early deadline

- Proposal Submission Notice:

1. Pre-Award is not authorized to submit a proposal to a federal agency requiring Research Security Training unless certification is provided by all senior/key personnel.
2. Certification must have been completed within 12 months of the proposal deadline to be valid.

NSF – RS Training

- Effective October 10, 2025
- NSF requires research security training certifications from proposers and individuals identified as senior/key personnel by the proposer.
- Proposers may utilize any training that addresses <u>cybersecurity, international collaboration, foreign interference, and rules for proper use of funds, disclosure, conflict of commitment, and conflict of interest</u>.

NSF, in partnership with the NIH, the DOE and the DOD, have provided four online research security training (RST) modules as a resource to awardee organizations. Subsequently, the SECURE Center developed an updated and condensed version of the four modules. The condensed RST module is designed to meet the government-wide RST requirement in Section 10634 of the CHIPS and Science Act of 2022 (42 U.S.C. § 19234). To that end, NSF, NIH, DOE, and DOD **all recognize completion of the condensed module as compliant with their respective RST requirements.**

NSF – RS Training

Research Security Training Requirement for Federal Award Personnel: In accordance with Section 10634 of the CHIPS and Science Act of 2022 (42 U.S.C. § 19234), each individual identified as a **senior/key person** must certify that they have completed the requisite research security training that meets the requirements specified in *Item 2 of Important Notice No. 149* **within 12 months prior to proposal submission**.

<u>Certifications</u> – AOR required to complete certification

1. Research Security Training for Senior/Key Personnel
2. Responsible and Ethical Conduct of Research (RECR) – IHEs only
   a. **Who**: undergrads, grads, postdocs, faculty, other senior/key
   b. **Training**: mentor training and mentorship, raise awareness of potential research security threats, export control, disclosure and reporting requirements.

Conflict of Interest or (FCOI) Committee

- WKU FCOI Disclosure Form
- WKU FCOI Research Policy
- WKU Policies: Research, Unit 2
- IRBNet Training Tools
- FCOI Committee Members

Financial Conflict of Interest

Beginning January 1, 2024, investigators will now only need to complete a single, one-time Financial Conflict of Interest (FCOI) disclosure each calendar year that will apply to all proposals being submitted as opposed to a disclosure for each grant submitted. We anticipate this will significantly reduce the administrative burden for faculty and staff – and especially for those who submit several proposals per year. See the quick links on this page for the annual WKU FCOI Disclosure Form as well as the WKU FCOI Research Policy.

If additional potential conflicts are identified within the year, investigators are required to submit an ad hoc disclosure within 30 days of discovering the potential conflict.

Click here to submit an annual or ad hoc disclosure: Visit IRBNet

The Conflict of Interest or (FCOI) Committee at work

- We are in the midst of updating our annual disclosure to include questions regarding conflicts of commitment and the Malign Foreign Talent Recruitment Program (MFTRP).
- We have also created a template for Conflict Management Plans moving forward.
- Our hope is to have all policies/procedures updated by the next annual disclosure call (November 15^{th})

Dr. Marguerita DeSander, Director SLPS, CEBS Associate Dean for Retention, Persistence, and Degree Completion, is the FCOI Chair

General Questions?


TIME FOR A
BREAK

WKU Procurement Training

Essential skills for effective purchasing

Grant Money is Still State Funds

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Grant Funds as State Money

Grant money received by WKU is treated as state funds once deposited into university accounts.

Compliance with Laws

All expenditures using grant funds must comply with state procurement laws and WKU policies.

Procurement Statute Reference

Kentucky Revised Statute KRS 45A.030(21) defines procurement to include grant-funded expenditures.

Managing Grant Projects

Project managers must understand legal and procedural responsibilities tied to grant funds.

Conflict of Interest

Definition of Conflict of Interest

A conflict occurs when personal or financial interests risk compromising impartial decision-making in procurement.

Examples of Conflicts

Examples include buying from family-owned businesses or having financial stakes in a vendor.

Disclosure Policy

Employees must disclose conflicts to uphold transparency and integrity in procurement processes.

Legal Guidelines

KRS 45A.110 outlines bidder responsibilities and disclosure requirements to ensure ethical vendor selection.

Personal Service Contracts (PSC)

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Purpose of PSCs

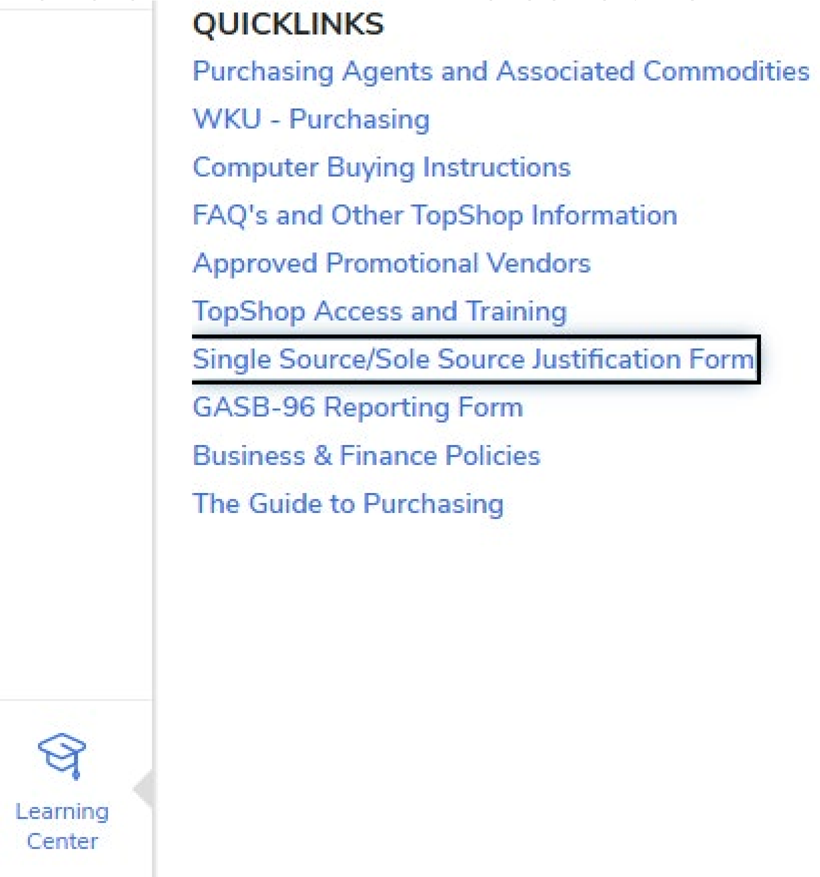
Personal Service Contracts are used for professional services like consulting, legal advice, and training engagements at WKU.

Contract Terms and Limits

PSCs require defined start and end dates and have dollar limits unless higher amounts are justified and approved.

Ensuring Proper Procedures

Departments must follow procedures and obtain necessary approvals when engaging external professionals using PSCs.



Single/Sole Source Form

- **Definition:** Noncompetitive procurement when only one vendor can provide the goods/services.
- **Requirements:**
  - Must submit **WKU Single/Sole Source Justification Form**
    – Located on **TopShop** → **Learning Center**
  - Must include **detailed justification** for why competition is not feasible
- **Reference:** KRS 45A.095 – Noncompetitive negotiation procedures.

Thank You

We are available to join your college or departmental meetings to gain a clearer understanding of your needs.

THANK YOU FOR ATTENDING!