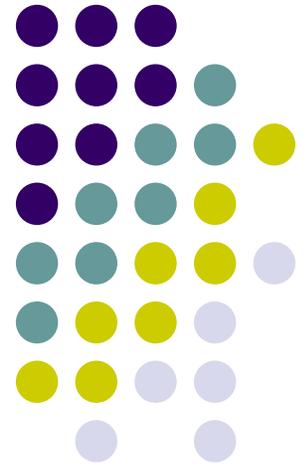
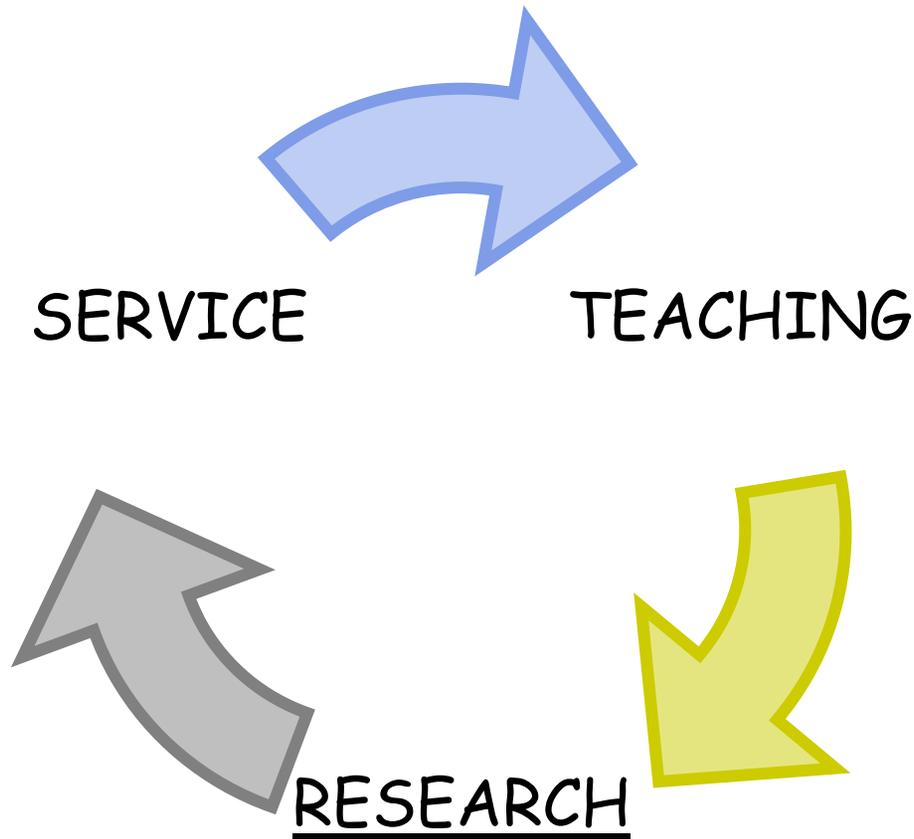


RESEARCH COMPLIANCE

Elizabeth N. Noel, PhD
Associate Vice President,
Research
Office of Research & Development



Research is the Foundation





Research Is ...

A CRITICAL COMPONENT of the INSTITUTIONAL MISSION

Prairie View A&M University is

- dedicated to excellence in teaching, **research** and service.
- committed to achieving relevance in each component of its mission by **addressing issues and proposing solutions through programs** and services
- designed to respond to the needs and aspirations of individuals, families, organizations, agencies, schools, and communities – both rural and urban.
- a state-assisted institution by legislative designation, serving a diverse ethnic and socioeconomic population.
- **a land-grant institution by federal statute.**

[Excerpts from University Mission statement, University Catalog, 2005-2007, p. 25.]



Research Is ...

REPRESENTED IN THE INSTITUTIONAL CORE VALUE OF RELEVANCE

PVAMU will respond to the need for highly literate, technologically competent graduates educated to excel in the 21st century work force; further, **the University will extend the products of its research** and service to address concerns and solve problems such as violence, abuse and misuse; drug and alcohol abuse; mental, physical, and psychological neglect; environmental injustice; and other forms of social dissonance that compromise the quality of life for the citizenry.

[Excerpts from the University Catalog, 2005-2007, p. 25.]

A CRITICAL UNIVERSITY GOAL

Increase Applied and Basic Research (Research/Discovery)

Research Is ...



- a systematic investigation
- development
- testing
- evaluation
- designed to contribute to generalizable knowledge

Source: TITLE 45, CODE OF FEDERAL REGULATIONS, PART 46.102



Research Is ...

- BASIC – exploration, investigation, development of new scholarly venues – the “What If”
- APPLIED – testing and evaluating the application of new and/or previous scholarly contributions to knowledge in a new venue – the “Yes We Can”



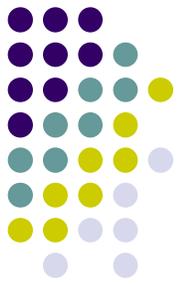
Research Is ...

Organized and Sponsored Research (research and development activities) that are:

- *separately budgeted* and accounted for
 - *externally sponsored*
by federal and non-federal agencies and organizations

Source: TAMUS Regulation 15.01.01, Administration of Sponsored Agreements-Research and Other

Research Is...



Sponsored Program Activities

Typically defined as ...
non-research projects and activities that are supported
in whole or in part with funds, materials, or other resources
*provided by sources outside
the University as grants, contracts, or cooperative agreements.*

Instruction and Training

special instructional activities
established by grant, contract, or cooperative agreement.

Other Activities

programs and projects which involve the performance of work,
i.e., community service programs.

- ***These activities can and should also be categorized as research.***

Research Is ...



Assessment

The systematic processes that identify, collect, review, use and prepare data/information about programs for the purpose of evaluating achievements and improving the effectiveness of the work.

Research as Assessment



Assessment Requires

- Strategic/Effectiveness Planning
- Agreement on program goals/objectives/outcomes
- Design and implementation of thoughtful approaches to assessment
- Involvement of individuals (stakeholders), on-and off-campus
- Selection or design and implementation of data collection approaches – direct and indirect
- Examination, sharing, and acting on the results
- Regular re-examination of the plan
- Implementation of revised plans

Research as Assessment



WHY ASSESS?

- The public demands it for accountability.
- The institution needs it for accreditation.
- The nation expects it as feedback for improvement of higher education, especially undergraduate education.

Therein,

ASSESSMENT helps us to provide data that we are achieving our goals.

Assessment and Research



ASSESSMENT AND REGULATORY COMPLIANCE

- Information obtained for the purpose of **documenting the effectiveness** of an institutional-wide component or a College/School, department, division or Center at the University and **intended to guide good practice** for the unit being assessed, does not require Regulatory Compliance Committee review or approval prior to commencing substantive work.
- **Information gathered during this effort CANNOT be used for any private or personal research purposes, i.e., presentation or publication, without prior approval of the University Regulatory Compliance Committee organized to help ensure the rights and welfare of participants in research activities.**

Assessment as Research



ASSESSMENT AND REGULATORY COMPLIANCE

- If it is determined, after information has been obtained through an assessment process, that the information could be used for presentation or publication, approval by a University Regulatory Compliance Committee must be sought and received prior to use of the information for either publication or presentation in any format other than as an internal institutional report.
- The **regulatory compliance committee** responsible for safeguarding the rights and welfare of human participants is the ***Institutional Review Board (IRB)***; for safeguarding the humane care and treatment of animals is the Institutional ***Animal Care and Use Committee (IACUC)***; and for activities involving Bio-hazards, recombinant DNA molecules, and radiation safety is the ***Institutional Biosafety Committee (IBC)***.

Assessment and Research



CLASSROOM/LABORATORY ACTIVITIES AND REGULATORY COMPLIANCE

- Research as normal classroom/laboratory activities designed to train students in research methods, usually do not fall within the federal definition of research. Course work in Research Methods should include information regarding Research Regulatory Compliance requirements for the conduct of research.
- Faculty members teaching Research Methods as normal classroom/laboratory activities should complete and submit to the Office of Research Regulatory Compliance, Office of Research and Development, the Classroom Research Project Protocol Application prior to the first class day during an enrollment period during which the course will be taught, but definitely prior to the collection of any data.

Research Is ...



Evaluation

- **The process of receiving the results of data collection and analysis and making a determination of the value of findings and action to be taken.**
- **Guides Outcomes**



Research Is ...

Outcomes - Statements that Describe

- 1) what we are expected to know;
- 2) what we have learned;
- 3) what we have achieved of a desired result or tangible destination;
- 4) what we are able to do;
- 5) what skills we have gained;
- 6) what attitudes we have developed; and
- 7) what actually happened by the time of project/program completion.

Research Compliance Is ...



- Recognizing that RESEARCH is the primary goal of your work
- Knowing the rules of the Research Game
- Following the rules of the Research Game
- Assuring that your Research work is Scholarly
- Ensuring that your Research work is based on Ethical practices and conduct

Research Compliance Is ...



REGULATORY COMPLIANCE – an indication that any research conducted with the intent to contribute to generalizable knowledge through publication or presentation within an academic discipline, including that originating from classroom or other institutional activities or that reach outside the classroom/laboratory, **MUST** meet the institutional Research Regulatory Compliance requirement and have available, upon request, an approved protocol for review. Undergraduate and graduate student research (theses and dissertations) clearly fall within this federal definition of research.



Research Compliance Is ...

ACCOUNTABILITY

- The application of Ethical Standards in Research and Scholarship.
- Ensuring honesty, accuracy and completeness in designing, carrying out, and reporting academic research --BASIC or APPLIED -- in all disciplinary fields, to include research proposals, laboratory records, progress reports, abstracts, theses, dissertations, oral presentations, internal reports, electronic media, and journal articles.

Research Compliance Is ...



ACCOUNTABILITY

ACCOUNTABILITY MEANS:

- Academic research **MUST** be conducted under the highest standards of honesty and integrity.
- Academic research, including all data, procedures, and findings, **MUST** be properly and thoroughly documented.

ACCOUNTABILITY MEANS:

- The creditability of academic research and scholarship depends on the integrity with which it is designed, conducted, documented, and communicated.
- We are **ALL** expected to reach or exceed all evaluation measures.

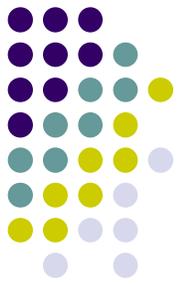
Research Compliance Is ...



ACCOUNTABILITY

ACCOUNTABILITY MEANS:

- **ALL members of the institutional community**, including students, staff, faculty, and administrators **share responsibility** for developing and maintaining ethical standards of research and scholarship.
- **WE are ALL** responsible and liable for our actions.



Research Compliance Is ...

ACCOUNTABILITY - An ASSURANCE

by the institution
that the

content, scope, quality, facilities, funding and conduct of all research and sponsored program activities under it's jurisdiction have followed all terms, conditions, and applicable guidelines relating to these activities.



Research Compliance Is ...

ACCOUNTABILITY MONITORED BY THE OFFICE OF RESEARCH AND DEVELOPMENT

Therefore,

Any MISCONDUCT in research or scholarship represented by fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research, must be reported.

Research Compliance Is ...



ACCOUNTABILITY MONITORED BY THE OFFICE OF RESEARCH AND DEVELOPMENT Means That

- All notations/official written reports of possible misconduct in Research must be documented.
- Following notion, an inquiry is conducted to determine the extent of the misconduct. If minor, minimal harm to the research participant, the case is resolved locally and documented in the file of the violator as the final disposition.
- If an investigation is required, the misconduct is major, significant long-term harm to the research participant, the case requires reporting of the misconduct to the controlling federal agency and the involvement of legal counsel for final disposition.



Research Compliance Is ...

ACCOUNTABILITY -- THE ASSURANCE THAT:

- ALL research activities respond to the Federal mandate for compliance.
- ALL proposed research plans/protocols respond to the federal assurance requirement, and therefore are reviewed by the:
 1. Institutional Animal Care and Use Committee (IACUC);
 2. Institutional Bio-safety Committee (IBC) for Bio-Hazards, Recombinant DNA, and Radiation Safety; and/or the
 3. Institutional Review Board (IRB) for Protection of Human Participants

Research Compliance is Regulatory



The **Institutional Animal Care and Use Committee (IACUC)** that oversees the humane care and treatment of vertebrate animals involved in ALL research, teaching, and demonstration projects, research training, and biological testing, sponsored and non-sponsored.

These activities must be reviewed and approved before the project begins and annually throughout the lifecycle of a project.

(Animal Welfare Act and Public Health Service Policy)

Research Compliance Is Regulatory



ANIMAL WELFARE ASSURANCE

- PVAMU has an approved Animal Welfare Assurance in accordance with the Public Health Service (PHS) policy for Humane Care and Use of Laboratory Animals. This assurance is applicable to all research, research training, experimentation, biological testing, and related activities, involving live vertebrate animals supported by the PHS and conducted at this institution or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.
- PVAMU is expected to adhere to corresponding and additional guidelines prescribed by the USDA under the Animal Welfare Act.

Research Compliance Is Regulatory



- PVAMU acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Animal Welfare Assurance. As partial fulfillment of this responsibility, the institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as other applicable laws and regulations pertaining to animal care and use.
- The IACUC has been organized to oversee compliance with the assurance.

Research Compliance Is Regulatory



The **Institutional Animal Care and Use Committee (IACUC)**, in response to this assurance, is expected to conduct, at least once every six months, a review of the institution's program for humane care and use of animals and inspect all of the institution's animal facilities. The specific areas for review include:

1. IACUC membership and functions
2. IACUC records and reporting requirements
3. Veterinary care/medical care
4. Personnel qualifications and training
5. Occupational Health and Safety of personnel
6. Housing and support areas
7. Cagewash
8. Aseptic surgery
9. Rodent surgery

Research Compliance Is Regulatory



The **Institutional Biosafety Committee (IBC)** oversees ALL research, teaching, or service activities, regardless of funding source, involving recombinant DNA molecules, radiation or bio-hazards.

ALL activities must adhere to the National Institutes of Health Guidelines for Research.

The IBC must review and approve the plan prior to commencing substantive work.

The protection of all employees, students and the public must be ensured.



Research Compliance Is Regulatory

- The **Institutional Review Board (IRB)** that oversees ALL research, teaching, or service activities, funded or not, and conducted by University personnel or students, or otherwise sponsored by the University, including sponsored projects/programs and service/continuing education/service learning activities, planned or conducted and **involving human participants**.
- ALL activities **MUST** implement prescribed procedures (Department of Health and Human Services) designed to safeguard the rights and welfare of human participants.
- IRB approval must be obtained prior to the conduct of any activity and the project must be reviewed at least annually for as long as it is active.

Research Compliance Is ...



One Measure of Institutional Effectiveness

Prairie View A&M University is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools to award Bachelor's, Master's and Doctoral degrees.

The *Principles of Accreditation* indicate that:

The Commission on Colleges expects an institution to dedicate itself to enhancing the quality of its programs and services within the context of its mission, resources, and capabilities, and to create an environment in which teaching, public service, research, and learning occurs.” (p. 3).

[Excerpts from the Resource Manual for the Principles of Accreditation:
Foundation for Quality Enhancement, 2005.]

Research Compliance Is ...



- Recognizing that RESEARCH is the primary goal of your work – the Foundation of teaching and service.
- Knowing the rules of the RESEARCH Game – Assurance and Accountability.
- Following the rules of the RESEARCH Game – Accountability and Effectiveness.
- Assuring that your RESEARCH work is Scholarly - Relevance
- Ensuring that your RESEARCH work is based on Ethical practices and conduct – Accountability and Effectiveness.

A Measure of INSTITUTIONAL EFFECTIVENESS.

Spring 2008