THE RESEARCH PROCESS

Presented by
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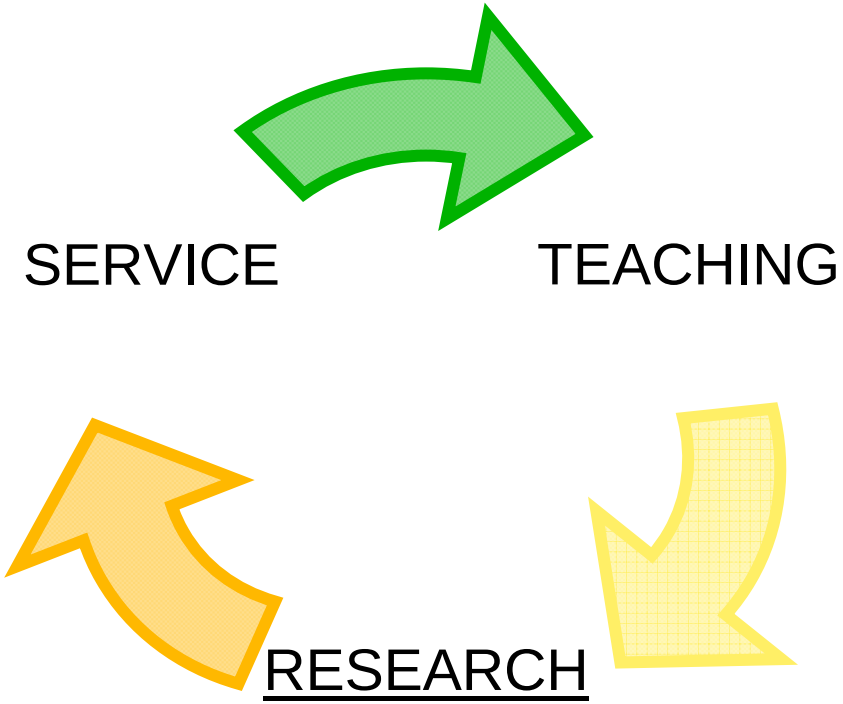
Research is the Foundation…



RESEARCH IS

- a systematic investigation, including research development, testing and evaluation;
- designed to develop or contribute to generalizable knowledge.

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

THE RESEARCH PROCESS

The Office of Research and Development

- Provides guidance to help ensure that all research is conducted in accordance with federal, state, and university regulations;
- Provides administrative support to the compliance committees;
- Develops and sustains an environment that is sensitive and humane in all aspects of research;
- Develops and delivers educational programs;
- Creates and fosters an acceptable climate for cooperative research;

THE RESEARCH PROCESS

The Office of Research and Development

Helps to Enforce

The Department of Health and Human Services (DHHS) policy that dictates the eligibility for receipt of any and all federal funds at the University are preceded by a commitment to actively comply with a number of federal regulations regarding research related activities.

THE RESEARCH PROCESS

RESEARCH ACCOUNTABILITY

- We are responsible and liable for our actions
- We are expected to reach or exceed all evaluation measures of accountability
- Academic research must be conducted under the highest standards of honesty and integrity and all data, procedures, and findings MUST BE properly and thoroughly documented.

- Ethics in Research and Scholarship

The creditability of academic research and scholarship depends on the integrity with which it is designed, conducted, documented, and communicated.

THE RESEARCH PROCESS

RESEARCH ACCOUNTABILITY

Ethical Standards in Research and Scholarship

- Emphasizes honesty, accuracy and completeness in designing, carrying out, and reporting academic research--basic, applied, demonstration--in all disciplinary fields, via research proposals, laboratory records, progress reports, abstracts, theses, dissertations, oral presentations, internal reports, and journal articles,.
- All members of the institutional community, including students, staff, faculty, and administrators share responsibility for developing and maintaining ethical standards of research and scholarship.

THE RESEARCH PROCESS

RESEARCH ACCOUNTABILITY

- MISCONDUCT in research or scholarship represents fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research.
- All notations or official reports of possible misconduct must be followed by an inquiry to determine if an investigation should be conducted with the final stage of adjudication of the case.

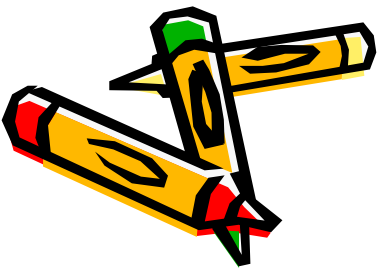
THE RESEARCH PROCESS

ACCOUNTABILITY

IS

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



THE RESEARCH PROCESS

COMPLIANCE
is the
Primary Method of Accountability
And the
ASSURANCE
that the University is following all terms, conditions and applicable guidelines relating to Research and Sponsored Programs.

The University is committed to COMPLIANCE through the maintenance of ethical standards and the creation of an environment suitable for the conduct of quality research.

THE RESEARCH PROCESS

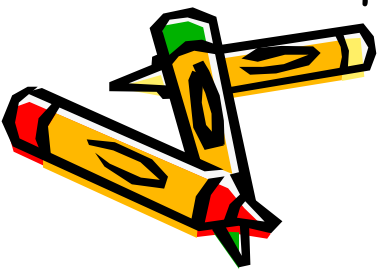
The Office of Research and Development

Helps to Ensure That

The University responds to Compliance with Federal Regulations through operation of a

RESEARCH COMPLIANCE OFFICE

The Research Compliance Office works with researchers through various review committees and related administrative activities to make a concerted effort to ensure the protection of human subjects, the humane treatment of vertebrate animals used in research and teaching, and special handling of bio-hazardous and radioactive materials.



THE RESEARCH PROCESS

The Office of Research Compliance Helps to Ensure That

University research activities with a federal mandate for compliance committee review and approval of the proposed research plan and protocols in response to the federal assurance requirement are reviewed by the:

1. Institutional Bio-safety Committee (IBC) for Bio-Hazards, Recombinant DNA, and Radiation Safety;
2. Institutional Animal Care and Use Committee (IACUC);
3. Institutional Review Board (IRB) for Protection of Human Participants

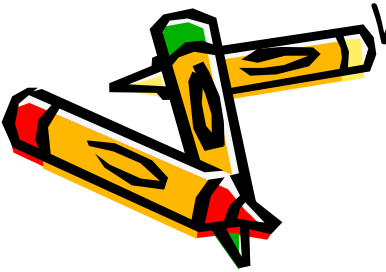
THE RESEARCH PROCESS

The Office of Research Compliance

Requires

- The submission of a protocol for comprehensive review by a Compliance Committee that must be submitted on or before the 15th of each month.
- Each Compliance Committee meets at least monthly on the second Monday (IRB), Wednesday (IBC) or Thursday (IACUC).
- An appropriately completed protocol, submitted by the stated deadline to the Office of Research Compliance, will receive a status response within 30 calendar days.

NO WORK ON ANY PROJECT SHALL BEGIN PRIOR TO WRITTEN APPROVAL FROM THE APPROPRIATE COMPLIANCE COMMITTEE(S).



THE RESEARCH PROCESS

Institutional Review Board (IRB)
for Protection of Human Participants

The Institution MUST agree to comply with the Department of Health and Human Services (DHHS) regulations on the protection of human subjects:
http://ohrp.osophs.dhhs.gov/polasur.htm

The Institution is responsible for ensuring that all sponsored research and related activities, planned or conducted by University personnel or students, involving human subjects will implement prescribed procedures designed to safeguard and protect their rights, safety, and welfare.

The IRB is charged with evaluating research studies in terms of the risk the research poses to human participants (subjects) and with reviewing the informed consent process according to the level of risk posed.

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB)
FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

- Risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risks.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from those participants would receive even if not participating.

THE RESEARCH PROCESS

- THE INSTITUTIONAL REVIEW BOARD (IRB) FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

- Selection of participants is equitable. The IRB should consider the purposes of the research and the setting in which the research will be conducted and be particularly mindful of the special problems or research involving vulnerable populations. Participants should share equally in foreseeable benefits and risks.

THE RESEARCH PROCESS

- THE INSTITUTIONAL REVIEW BOARD (IRB) FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

- Informed consent is sought, and will be obtained, from each prospective participant or the participant's legally authorized representative
- Informed consent is appropriately documented
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB) FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data

- Additionally, when some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, or mentally disabled, economically disadvantaged, or educationally disadvantaged persons) additional safeguards are included in the study to protect the rights and welfare of these participants.

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB) FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

Assessment of Risks and Benefits

- When approving research, the IRB must assess whether the anticipated benefit of the research – either new knowledge or improved health for the research participants – justifies inviting anyone to undertake the risks.

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB) FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

Assessment of Risks and Benefits

- Risks to individuals are classified as physical, psychological, social, legal, and economic. In the process of determining what constitutes a risk, only those risks that may result from the research, as distinguished from those associated with therapies participants would undergo even if not engaged in research, should be considered.

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB)
FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

Assessment of Risks and Benefits

Once risks have been identified, the IRB must assess whether the research poses minimal or greater than minimal risk.

Minimal risk is defined such that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB)
FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

The concept of minimal risks is used in the Federal policy for three purposes:

1. It guides the IRB to determine if the proposed research should be reviewed by the full Board or if it may qualify for expedited review.
2. It is used to determine what research can proceed without consent.
3. It is used to decide when documentation of subject consent may be waived.

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB) FOR PROTECTION OF HUMAN PARTICIPANTS

Risks to participants are minimized. Researchers should include strategies for reducing risks in the protocol. For example:

- Precautions, safeguards, and alternatives should be incorporated into the protocol to reduce the probability of harm or to limit its severity or duration

- Determine whether the researchers are competent in the planned area and whether they serve dual roles (e.g., as clinician and researcher) that may result in conflicts of interest and lead to a "therapeutic misconception" being held by the research participant

THE RESEARCH PROCESS

THE INSTITUTIONAL REVIEW BOARD (IRB)
FOR PROTECTION OF HUMAN PARTICIPANTS

In order to approve research, the IRB must ensure the following requirements are satisfied:

- Assessment of whether the research design will yield useful data, so that research participants are not exposed to risks without sufficient justification

NOTICE

The IRB must be notified of any unanticipated problem involving risks to participants or others, including physical or psychological injury to participants, improper disclosure of private information, economic loss, or other potentially harmful occurrences.

THE RESEARCH PROCESS

The Institutional Review Board
for Protection of Human Participants
Has the responsibility to:

- Ensure that All continuing research activities involving human subjects have on file with the Research Compliance Office, an approved Standard Operating Procedure (SOP), including a health management plan, and that same is posted in the designated research site (s)
- Consider adverse events, interim findings, and any recent literature that may be relevant to the research
- Assess suspected or alleged protocol violations, complaints expressed by research participants, or violations of institutional policies

THE RESEARCH PROCESS

The Institutional Review Board
for Protection of Human Participants
Has the responsibility to:

- Review the full protocols for planned research studies to ensure that, in its judgment, the research meets the criteria
- Confirm that the research plans do not expose participants to unreasonable risks
- Conduct continuing review of approved research at intervals commensurate with the degree of risk of the participants, but not less than once a year, to ensure that human participant protections remain in force

THE RESEARCH PROCESS

The Institutional Review Board
for Protection of Human Participants
Has the authority to:

- Require that information be given to participants when the IRB determines that this information would add to the protection of their rights and welfare
- Require documentation of informed consent or allow waiver of documentation
- Determine if the research involves no greater than minimal risk, the study must be reviewed by an IRB, but may be eligible for expedited review (review by the IRB Chair or a specified voting member, rather than by the full Board).

THE RESEARCH PROCESS

The Institutional Review Board
for Protection of Human Participants
Has the authority to:

- Approve, disapprove, or terminate all research activities that fall within its local jurisdiction according to relevant Federal regulations and institutional policy
- Require modifications in protocols, including previously approved research

THE RESEARCH PROCESS AND GRADUATE STUDY

- RESEARCH and graduate study are interlinked, interconnected, interrelated, and mutually supportive
- The Graduate School is a graduate student's primary source of information about study for an advanced degree.
- Graduate programs are offered under the joint supervision of the Graduate School and the College/School offering the degree programs.

THE RESEARCH PROCESS AND GRADUATE STUDY

GRADUATE THESIS AND DISSERTATION COMMITTEES

- The Research Committee Chair should be an individual with research foci in an area of major interest to the Graduate Student.
- The Research Committee Members should be individuals that can provide support for the Graduate Student and the Thesis/ Dissertation Committee Chair in the planning and implementation of Graduate Student Research.

THE RESEARCH PROCESS AND GRADUATE STUDY

GRADUATE THESIS AND DISSERTATION COMMITTEES

- The Chair of the Graduate Research Committee should be selected by the STUDENT in consultation with the Academic Advisor, the Graduate Program Coordinator/Department Head, and the Dean.
- Members of Departmental faculty serve as Chair of the Thesis/Dissertation Committee.
- The Chair of the Graduate Research Committee may or may not be the same person serving as the Academic Advisor.

THE RESEARCH PROCESS AND GRADUATE STUDY

The Research Plan

The Research Plan is developed in consultation with the Thesis/Dissertation Committee Chair and Committee members as required by the Academic Program Department

Upon completion of the plan, secure the review, comments, revision, and approval of the Thesis/Dissertation Committee

Submit the Research Protocol
to the appropriate Research Compliance Committee
for Review and Approval

"NO EXCEPTIONS"

IRB PROTOCOL APPLICATION

- Checklist for Human Subject Protocols (Use checklist as a guide to the content of the application)

- Part A. Summary Cover Sheet
  - Section I – Principal Investigator/Faculty Advisor Agreement
  - Section II – Funding, Training/Education and Protocol-Related Conflict of Interest
    Attach certification of completion of Human Subject Participant Electronic Training (HSPET)
    Attach the Protocol-Related Conflict of Interest (COI) Disclosure Form, if applicable
    [ALL investigators and other key personnel MUST sign form]

IRB PROTOCOL APPLICATION

- Part B. Protocol Format

  Section III: General Information

  Category of participants

  Location for study

  Duration of project – begin/end

  Number of subjects

  PVAMU

  Other location (s)

IRB PROTOCOL APPLICATION

Part B. Protocol Format

Section IV – Research Plan

- Statement of Purpose - What do you intend to do? Goal (s), Objectives/Hypothesis

  [IRB Protocol, Section IV, Item 1]

- Background - Why is the work important? Significance
- What has already been done? Review of Literature, Preliminary Study Data, Progress Reports

  [IRB Protocol, Section IV, Item 2]

IRB PROTOCOL APPLICATION

- Part B. Protocol Format
  Section IV – Research Plan
- How are you going to do the work?

Research Design and Procedures to be used to accomplish specific aims of the project

Describe any new methodologies and why they are used instead of existing methods

Discuss potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims

[IRB Protocol, Section IV, Item 3]

IRB PROTOCOL APPLICATION

Part B – Protocol Format
Section IV – Research Plan

Statistical Considerations

How will data be collected, analyzed, and interpreted?

Include number of subjects
Statement about statistical power of the study to test the major hypothesis
Provide a summary plan for data analysis
[IRB Protocol, Section IV, Item 4]

IRB PROTOCOL APPLICATION

Part B – Protocol Format

Section IV – Research Plan

- How are you going to do the work?

Probable Duration of Project

Provide a sequence or time table for the project

[IRB Protocol, Section III, Item 3]

Recruitment Procedures

Point out any procedures, situations, or materials that my be hazardous to personnel and the precautions to be exercised

[IRB Protocol, Section V, Items 1 & 2]

IRB PROTOCOL APPLICATION

- Part B. Protocol Format
- Section V – Human Participants/ Subjects
    - Subject Population – Who
    - Vulnerable Subjects – Who
    - Relationship to Subjects, if any

IRB PROTOCOL APPLICATION

Part B – Protocol Format

Section VI – Consent/Assent Procedures

Section VII – Protection of Research Subjects

Section VIII – Research Alternatives and Economic Considerations

Section IX – Formatting Guidance

Section X – Research Involving Drugs, Devices or Biologics

THE RESEARCH PROCESS

RESEARCH/DISCOVERY IS THE FOUNDATION FOR TEACHING/LEARNING AND SERVICE/ENGAGEMENT

WE MUST ALL WORK TOGETHER TO AFFIRM AN INFRASTRUCTURE THAT ENFORCES AND ASSURES 100% COMPLIANCE

RESEARCH AND GRADUATE STUDY

Completing the Research Plan

- The approved and signed copy of the thesis, dissertation or project report is an indication that the Graduate Student has met the standards as outlined by the respective Program. A copy of the final signed product should be submitted to the Graduate School. Include in the final product, a copy of the Approved Research Protocol that authorized the research study.

RESEARCH AND GRADUATE STUDY

Completing the Research Plan

- The style and format for oral and written presentations within a disciplinary area should be a continuous process initiated during the first semester of enrollment.
- The graduate thesis, dissertation or project report must be prepared in a style and format that is prescribed by the specific degree program.
- An oral examination is required of thesis and dissertation students. The oral examination is designed to test verbal and explanatory abilities of students as they explain and defend their research.

THE UNIVERSITY RESEARCH PROCESS AND THE PVAMU MISSION

- Dedicated to excellence in teaching, research and service
- Committed to achieving relevance in each component of the 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

(Mission updated July 18, 2002)

THE UNIVERSITY RESEARCH PROCESS AND THE PVAMU MISSION

- A state-assisted institution by legislative designation
- A land-grant institution by federal statute
- Positioned to serve a diverse ethnic and socioeconomic population
- Committed to prepare undergraduates in a range of careers …
- Committed to advanced education through the master's degree …

(Mission updated July 18, 2002)

THE UNIVERSITY RESEARCH PROCESS AND THE PVAMU MISSION

- Committed to expanding its advanced educational offerings to include multiple doctoral programs
- Target service area includes the Texas Gulf Coast Region; the rapidly growing residential and commercial area known as the Northwest Houston Corridor; and urban Texas centers likely to benefit from specialized programs and initiatives in Nursing, Juvenile Justice, Architecture, Education, and Social Work

(Mission updated July 18, 2002)

THE UNIVERSITY RESEARCH PROCESS AND THE PVAMU MISSION

- Service programs are delivered primarily through the Cooperative Extension Program
- RESEARCH FOCI include extending knowledge in ALL disciplines offered and incorporating RESEARCH-based experiences in both undergraduate and graduate students' academic development

(Mission updated July 18, 2002)

THE UNIVERSITY RESEARCH PROCESS AND PVAMU GOALS

- Strengthen the quality of academic programs
- Improve the academic indicators of the student body
- Increase Applied and Basic Research
- Strengthen environmental health and safety programs on campus
- Achieve (and maintain) financial stability

THE UNIVERSITY RESEARCH PROCESS AND PVAMU GOALS

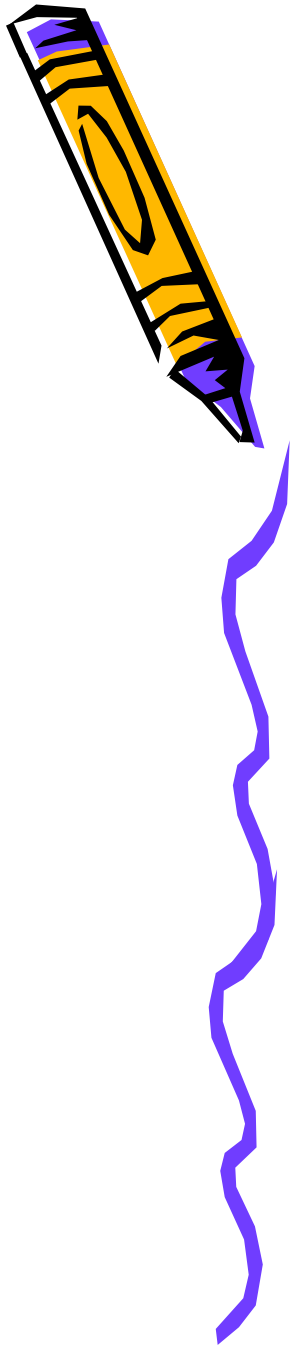
- Increase the efficiency of University operations
- Promote programs that contribute to student success
- Strengthen University advancement programs including fund-raising
- Increase and enhance the visibility and awareness of the University to the community/All Stakeholders

THE UNIVERSITY RESEARCH PROCESS

- The mission of an organization guides direction - goals
- The goals of an organization guide operation – performance
- The performance of an organization is determined by the actions of the PEOPLE

PRAIRIE VIEW A&M UNIVERSITY was established by the Texas State Legislature in the Year 1876.
PRAIRIE VIEW A&M UNIVERSITY is a member of the Texas A&M University System and is accredited by the COMMISSION ON COLLEGES OF THE SOUTHERN ASSOCIATION OF COLLEGES and SCHOOLS to award Bachelor, Master and Doctoral degrees.

RESEARCH AND THE ORGANIZATION



PVAMU is organized into four units:

- Academic and Student Affairs
- **Research and Development**
- Institutional Relations and Public Service
- Finance and Administration

ALL units are
interconnected and interrelated.

RESEARCH AND THE ORGANIZATION

The Office of RESEARCH and DEVELOPMENT at PVAMU

consists of three major components -

- Research Administration
- Institutional Development
- Alumni Affairs

RESEARCH AND THE ORGANIZATION

The Office of Research

and Development

assumes responsibility for advancing the mission of the University by helping it to meet goals related to the Research and Development through implementation of objectives specific to the Research [and Development] Process

RESEARCH AND THE ORGANIZATION

The Office of Research and Development supports the University through guidance for the active pursuit of grants, contracts, technology transfer, and strategic partnerships with other universities, federal and state agencies, other organizations, and the private sector (corporations, foundations, and individuals) for enhancement of the research, education and service mission of the University.

RESEARCH AND THE ORGANIZATION

RESEARCH IS CATEGORIZED AS

- University Research – all research and development activities that are *separately budgeted* and accounted for by the institution under an internal application of institutional funds.
- Departmental Research – all research development and scholarly activities that are not organized research and consequently, are *not separately budgeted* and accounted for.

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

RESEARCH AND THE ORGANIZATION

RESEARCH IS CATEGORIZED AS

- Organized Research – all research and development activities of an institution that are *separately budgeted* and accounted for.
- Sponsored Research – all research and development activities that are *externally sponsored* by federal and non-federal agencies and organizations.

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

RESEARCH AND THE ORGANIZATION

Sponsored Program agreements are typically for 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.

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

RESEARCH AND GRADUATE STUDY

- The **Graduate Student** is held fully responsible for ascertaining and following the procedures and regulations applicable to the chosen program of study.

NOTE

- Programs, regulations, and course offerings are subject to modification and/or deletion at any time by action of appropriate University authorities.

RESEARCH AND GRADUATE STUDY

- The Academic Advisor is assigned by the Program during the first semester of graduate school enrollment.
- The Academic Advisor guides the student for the purpose of planning and obtaining approval of the plan of study and for enrolling in classes.
- The Academic Advisor continues interactions with the student to discuss objectives, course selection and sequencing, and other degree/program related matters.

THE UNIVERSITY RESEARCH PROCESS

THE ASSURANCE STATEMENT IS

- An indication the Institution has made to the Federal Government that it will Review and Approve each Research Plan for Compliance.
- Documentation of Compliance Committee review and approval that MUST be certified at the time of final award for funded projects, and PRIOR to any work that begins on any project.
- Funded and non-funded research requires the same levels of approval and oversight.

THE UNIVERSITY RESEARCH PROCESS

THE ASSURANCE STATEMENT

- Institutions receiving federal funding for RESEARCH are responsible for protecting human subjects, providing humane treatment of animals, and monitoring the use of recombinant DNA.

- To provide for adequate discharge of this responsibility, Federal policy requires an ASSURANCE by the Institution, signed by the Authorized Organizational Representative (AOR), that appropriate committees have carried out the initial review of protocols and will conduct continuing reviews of supported projects. The Federal agency requires that the Institution cite the date that an appropriate committee issued an approval or exemption.

THE UNIVERSITY RESEARCH PROCESS

The Office of Research and Development

- Aids in developing and implementing multidisciplinary research endeavors;

And Requires

- The **University Committee on Research (UCOR)** as an advisory body to the Vice President for Research and Development. The Committee provides advice on planning for scientific development and needed support services; establishes allocation priorities; and deals with philosophical, legal, ethical, or moral questions concerning the conduct of science.

THE UNIVERSITY RESEARCH PROCESS

PRESENTATION CONTENT

- RESEARCH and Institutional Mission
- RESEARCH and Institutional Goals
- RESEARCH and The ORGANIZATION
- The Office of RESEARCH and DEVELOPMENT
- RESEARCH DEFINED and CATEGORIZED
- RESEARCH and GRADUATE STUDY
- RESEARCH ACCOUNTABILITY
- RESEARCH ASSURANCE
- THE OFFICE OF RESEARCH COMPLIANCE
- THE IRB (Institutional Review Board for Protection of Human Participants

THE RESEARCH PROCESS

Institutional Review Board (IRB)
for Protection of Human Participants

The Expedited Review

Limited in use to studies

- that clearly have minimal risk to human participants
- with minor changes in previously approved research during the one year period or less from original approval

THE RESEARCH PROCESS

Institutional Review Board (IRB)
for Protection of Human Participants
Key Definitions

- Human Subject – a living individual about whom the investigator (professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- Research – a systematic investigation, including research development, testing and evaluation, designed to develop generalizable knowledge, including demonstration and service programs.

THE RESEARCH PROCESS

- Institutional Review Board (IRB) for Protection of Human Participants

Key Definitions

- Intervention – both physical procedures by which data are gathered and manipulations of the subject that are performed for research purposes.
- Interaction – communication or interpersonal contact (e.g., surveys) between investigator and subject.
- Private Information – individually identifiable, but the individual can reasonably expect will not be made public.

THE RESEARCH PROCESS

Institutional Review Board (IRB)
for Protection of Human Participants

A Protocol may be classified as Exempt, after IRB review if:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to them
- any disclosure of the human participant's responses outside the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation

THE RESEARCH PROCESS

The Institutional Review Board
for Protection of Human Participants

A Protocol may be classified as Exempt, after IRB review if:

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

- the participants are elected or appointed officials or candidates for public office
- federal statute(s) require(s) without exception that the confidentiality of personally identifiable information be maintained throughout the research and thereafter

THE RESEARCH PROCESS

The Institutional Review Board
for Protection of Human Participants

A Protocol may be classified as Exempt, after IRB review if:

4. 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 researcher in such a manner that participants cannot be identified, directly or through identifiers linked to them
5. Research and demonstration projects conducted by or subject to the approval of Federal department or agency heads and designed to study, evaluate, or otherwise examine public health benefits or service programs
6. Taste and food quality evaluation and consumer acceptance study.

NOTE: A PROTOCOL MUST BE SUBMITTED TO THE IRB FOR REVIEW AND DETERMINATION OF EXEMPT STATUS.

THE RESEARCH PROCESS

The Institutional Review Board
for Protection of Human Participants

EXEMPTIONS DO NOT APPLY to:

- research involving prisoners, fetuses, pregnant women, or newborns
- in item 2 to children, except in research involving observations of public behavior when the researcher(s) do not participate in the activities being observed
- Interviews, surveys, and interactive observations are NOT EXEMPT, while educational tests and non-interactive observations are exempt

THE RESEARCH PROCESS

RESEARCH COMPLIANCE IN CLASS/LABORATORY ACTIVITIES

Research and normal classroom/laboratory activities designed to train students in research methods *usually* do not fall within the federal definition of research.

Faculty members teaching research methods as normal classroom/ laboratory activities, should complete and submit to the Office of Research Compliance, the Classroom Research Project Protocol Form. Include a copy of the course syllabus. The Protocol will be reviewed and, if complete, approved by the respective Compliance Committee.

THE RESEARCH PROCESS

RESEARCH COMPLIANCE IN CLASS/LABORATORY ACTIVITIES

Course work in Research Methods should include information regarding Research Compliance requirements for the conduct of research.

HOWEVER,

Undergraduate or graduate student research activities, which reach outside of the classroom/laboratory, may fall under the federal definition of research depending upon the type of interaction with the research participant(s).

THE RESEARCH PROCESS

RESEARCH COMPLIANCE IN
CLASS/LABORATORY ACTIVITIES

HOWEVER,

Graduate theses and dissertations are clearly research and fall within the Institutional Compliance Requirement. These documents MUST have an approved protocol included in the final copy.

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, MUST meet the Institutional Compliance Requirement and have available an approved protocol for review upon request.

THE UNIVERSITY RESEARCH PROCESS

Institutional Compliance Committees

- Have member(s) who are knowledgeable about and experienced in working with vulnerable categories of subjects, i.e., children, prisoners, pregnant women, or physically or mentally disabled persons (IRB specific)
- Provide guidance to colleagues and students participating in research and sponsored program activities
- Require College/School/Department recommendation and support. Selected individuals should be given Performance credit for providing committee service to the University

THE UNIVERSITY RESEARCH PROCESS

Institutional Compliance Committees

- Expect the full participation of the members for the review and recommended status for each Protocol
- Must have members with documentation of the completion of Certification (IRB) and/or specialized training in the Designated Focus Area – IRB, IACUC, and/or IBC. Documentation of Certification (IRB) and other specialized training must be submitted to and retained in the Office of Research Compliance.

THE UNIVERSITY RESEARCH PROCESS

Institutional Compliance Committees

- Composed primarily of faculty, professional and support staff that are recommended by the unit chief administrator
- Have a minimum of five members – at least one with primary concerns in scientific areas; one with primary concerns in nonscientific areas; one member not affiliated with the institution
- Have diversity regarding race, gender, cultural heritage, and sensitivity to issues such as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of research participants