

THE RESEARCH PROCESS

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



THE RESEARCH PROCESS

RESEARCH IS . . .

- a systematic investigation - 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

RESEARCH CATEGORIES AT PVAMU

- **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

THE RESEARCH PROCESS

RESEARCH CATEGORIES AT PVAMU

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

THE RESEARCH PROCESS

RESEARCH CATEGORIES AT PVAMU

Sponsored Program Agreements, although typically these are 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*, ***they may also be categorized as research.***

1. Instruction and Training

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

2. Other Activities

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

THE RESEARCH PROCESS

The OFFICE of RESEARCH REGULATORY COMPLIANCE

Requires:

- The **submission of a protocol application** for comprehensive review by a Research Regulatory Compliance Committee.
The application must be submitted on or before the 15th of each month.
- Each Research Regulatory Compliance Committee shall meet at least monthly during the second week of the month - Monday (IRB), Wednesday (IBC) or Thursday (IACUC).
- A Regulatory Compliance Committee response to an application will occur within 30 calendar days from the review by the appropriate committee.

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

THE RESEARCH PROCESS and UNIVERSITY EXPECTATIONS

ADHERENCE TO RESEARCH REGULATORY COMPLIANCE RULES IN ALL RESEARCH ACTIVITIES INCLUDING CLASSROOM/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 application will be reviewed by the appropriate committee (s) and NOTIFICATION of status will be provided within 30 days of submission. The approval process for the class eliminates the need for individual student protocol applications.

THE RESEARCH PROCESS and UNIVERSITY EXPECTATIONS

ADHERENCE TO RESEARCH REGULATORY COMPLIANCE RULES IN ALL RESEARCH ACTIVITIES INCLUDING CLASSROOM/LABORATORY ACTIVITIES

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

HOWEVER,

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

THE RESEARCH PROCESS and UNIVERSITY EXPECTATIONS

ADHERENCE TO RESEARCH REGULATORY COMPLIANCE
RULES IN
ALL RESEARCH ACTIVITIES
INCLUDING
CLASSROOM/LABORATORY ACTIVITIES

HOWEVER,

Graduate theses and dissertations are clearly research and fall within the Institutional Research Regulatory Compliance Requirement. These documents **MUST** have an approved protocol prior to beginning work on the project. A copy of the approval letter **MUST** be 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 Research Regulatory Compliance Requirement and have available an approved protocol for review upon request.

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

- 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.

THE RESEARCH PROCESS 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 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

GRADUATE THESIS AND DISSERTATION COMMITTEES

- The Research Committee Chair should be an individual selected by the Graduate Student with research foci in an area of mutual 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

The Research Proposal, Prospectus or 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

THEN

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

“NO EXCEPTIONS”

THE RESEARCH PROCESS and GRADUATE STUDY

Completing the Research Process

- 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 RESEARCH PROCESS and GRADUATE STUDY

Completing the Research Process

- 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.**

The Research Proposal, Prospectus or Plan

- The Research Proposal, Prospectus or Plan is the forerunner for the Thesis or Dissertation
- In most instances, the Thesis or Dissertation is a FIVE chapter document including the following:
 - Chapter 1 – Introduction
 - Chapter 2 – Literature Review
 - Chapter 3 – Methodology
 - Chapter 4 – Presentation and Analysis of Data
 - Chapter 5 – Results, Conclusions and Recommendations

The Research Proposal, Prospectus or Plan

- The Research Proposal, Prospectus or Plan is the forerunner for the Thesis or Dissertation
- In most instances, the Research Proposal is a THREE chapter document.

Chapter 1 – Introduction – a reflection of the current situation as it relates to the problem.

Introduction to the Problem

Background of the Study

Statement of the Problem (What do you intend to do?)

Purpose of the Study

Rationale

Research Questions/Hypotheses

Significance of the Study (Why is the study important?)

Definition of Terms

Assumptions and Limitations

Nature of the Study

Organization of the Remainder of the Study

The Research Proposal, Prospectus or Plan

- In most instances, the Research Proposal is a THREE chapter document.
- **Chapter 2 – Literature Review**
 - The theoretical context of the study.
 - A limited selection of literature perceived to be the best, most relevant and recent writings on the topic
 - A notation of studies previously conducted that this study will build upon
 - A critical analysis of all works included in the review of literature should be evident in the writing to include any omissions or shortcomings that influence the current proposed work

NOTE: Reference materials older than five (5) years should be avoided unless classified as a “CLASSIC” in the discipline.

The Research Proposal, Prospectus or Plan

- In most instances, the Research Proposal is a THREE chapter document.
- **Chapter 3 – Methodology**
 - Describe how the project work is going to be done – the Research Design and Procedures to be used to accomplish specific aims of the project.
How will data be collected, analyzed, and interpreted?
 - 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.
 - Provide a sequence or time table for the project.
 - Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

NOTE: The description of methodology should be clear to enable another researcher to replicate or repeat the study.

The Research Proposal, Prospectus or Plan

- The Research Proposal, Prospectus or Plan is the forerunner for the Thesis or Dissertation
- In most instances, the Thesis or Dissertation is a FIVE chapter document. These two chapters are prepared after completing data collection and analysis.
- Chapter 4 – Presentation and Analysis of Data
 - A summary of the new information obtained during the study. Findings are reported verbally, graphically and/or numerically.
- Chapter 5 – Results, Conclusions and Recommendations
 - The reporting of the Results focuses on clarifying the meaning of new information discovered and uses of this information to answer the research questions and to retain or reject the hypotheses. The Conclusions may note research opinions. The Recommendations should guide future research.

The Research Proposal, Prospectus or Plan

- Research Regulatory Compliance Committee (IACUC, IBC, and/or IRB) review is a natural part of the research planning process.
- Once the Committee has given approval to your plan, the information required for the Protocol Application is at your fingertips. Complete the appropriate form and forward to the appropriate Research Regulatory Compliance Committee for review and action.
- Participate in the Compliance Committee meeting during which your application will be discussed. Be prepared to answer questions and respond immediately following the meeting if concerns were noted and changes are required.

The Research Plan and the IRB Protocol Application

Checklist for Human Subject Protocols

Use the checklist as a guide and ensure that ALL items in the Protocol Application have been addressed. ALL blocks on the checklist should be checked or marked N/A, or your application is not complete.

- **Part A. Summary Cover Sheet**
 - **Project Title**
 - **Principal Investigator**
 - **Campus Address, Telephone, Fax; E-mail, Cell**
 - **New Submission or Resubmission**
- **Section I: Principal Investigator/Faculty Advisor Agreement**
- **Section II: Funding, Training/Education and Protocol-Related Conflict of Interest**
 - Attach Human Subject Protection Education/Training (HSPET) certification
 - Attach the Protocol-Related Conflict of Interest (COI) Disclosure Form, if applicable
 - Signature Page [ALL investigators, other key personnel, and administrative supervisors MUST sign the signature page in Section II]

The Research Plan and the IRB Protocol Application

Part B. Protocol Format

Section III: General Information

- Item 1. Type of Subjects (check all that apply)
- Item 2. Location of Study (Where will the study be conducted?)
 - PVAMU, specify site
 - Other location (s)
- Item 3. Probable Duration of Project (Provide a sequence or time table for the project)

The Research Plan

- Chapters 1 and 3
- Chapter 3
- Chapter 3

The Research Plan and the IRB Protocol Application

- **Item 4. Number of Subjects (Include the number of subjects for each location)**
 - Chapter 3

The Research Plan and the IRB Protocol Application

Part B. Protocol Format Section IV – Research Plan

- **Item 1. Statement of Purpose**
 - What do you intend to do?
 - Goals
 - Objectives
 - Research Questions
 - Hypothesis
- **Item 2. Background**
 - Why is the work important?
 - Significance
 - What has already been done?
 - Review of Literature
 - Preliminary Study Data
 - Progress Reports

The Research Plan

- Chapter 1
- Chapter 2

The Research Plan and the IRB Protocol Application

Part B. Protocol Format

Section IV – Research Plan

- Item 3. The Research Plan
 - Describe the study design and research procedures as they will directly affect the subjects. Tell 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

The Research Plan

- Chapter 3

The Research Plan and the IRB Protocol Application

Part B – Protocol Format Section IV – Research Plan

- Item 4. 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

The Research Plan

- Chapter 3

The Research Plan and the IRB Protocol Application

Part B. Protocol Format Section V – Human Participants/ Subjects

- Item 1. Recruitment Procedures
 - How will subjects be identified, contacted, and recruited?
(Include copies of all recruitment materials – flyers, telephone scripts, introductory letters)
- Item 2. Inclusion/Exclusion
 - Indicate criteria to be used to determine subject participation
- Item 3. Subject Population
 - Detailed description of proposed participants. Characteristics of the population to include anticipated number, age range, health status.

The Research Plan

- Chapter 3
- Appendix to Protocol should include flyers, telephone scripts, introductory letters
- Chapter 3
- Chapter 3

The Research Plan and the IRB Protocol Application

Protocol Application

Section V: Human Participants/ Subjects

- Item 4. Vulnerable Subjects
(Refer to Section III, Item 1. If you checked any of the blocks in Item 1, you have vulnerable subjects in your research). Therefore,
 - Identify the population and provide a justification for their involvement.
 - Note safeguards to protect their rights and welfare.
- Item 5. Indicate any relationship with participants other than as a researcher. If relationship exists, explain.

The Research Plan

- Chapter 3

- Chapter 3

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section VI – Consent/Assent Procedures

- Item 1. Consent Personnel
- Item 2. Assessment of Capacity to Consent, if applicable
- Item 3. Process of Consent
Indicate setting and conditions in which consent will be obtained.
(Review Consent Form checklist for required information and conditions)
- Item 4. Non-English Speaking Subjects (If applicable, how will you ensure comprehension?)

The Research Plan

- Appendices to the Protocol Application should include all forms
- Chapter 3

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section VI – Consent/Assent Procedures

- Item 5. Parental Permission and Assent – if minors are involved, explain how parental permission and child assent will be obtained.
- Item 6. Documentation of Consent – specify forms that will be used. Attach copies of all to protocol application.
- Item 7. Waiver of Consent – If requested, address question under waiver of consent and/or waiver of signed consent.

The Research Plan

- Appendix to Protocol Application

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section VI – Consent/Assent Procedures

- Item 8. HIPAA Authorization – If the research involves the creation, use or disclosure of private health information, the HIPAA Authorization Form and/or a request for waiver must be attached.

The Research Plan

- Appendix to Protocol Application

The Research Plan and the IRB Protocol Application

Part B – Protocol Format Section VII – Protection of Research Subjects

- Item 1. Risks – cite the reasonable foreseeable risks, discomforts, or inconveniences associated with participation.
- Item 2. Minimizing Risks – note how risks noted in Item 1 will be minimized.
- Item 3. Data and Safety Monitoring Plan – a plan that indicates the overall risks, addresses attributes and grading of adverse events and describes procedures for monitoring ongoing progress of the research and reporting adverse events.

The Research Plan

- Chapter 3
- Chapter 3
- Chapter 3

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section VII – Protection of Research Subjects

- Item 4. Confidentiality – respond completely to questions in items a-h
- Item 5. Potential Benefits – note any benefits reasonably expected to result from the research for participants or for society at large.

The Research Plan

- Chapter 3
- Chapter 3

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section VIII – Research Alternatives and Economic Considerations

- Item 1. Alternatives – will study offer treatments? If yes, what alternatives are available outside the research?
- Item 2. Payments for Participation (Economic Considerations)
 - describe any payments to be made and the conditions for receiving.
 - Costs for participation – describe all possible costs for participation in the research as outlined.
 - In Case of Injury – note how participants will be treated in the event of injury during study participation.

The Research Plan

- Chapter 3

- Chapter 3

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section IX – Formatting Guidance.

Please follow instructions given.

The Research Plan

Format according to
guidance provided by
the Department/School/
College of study

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section X – Research Involving Drugs, Devices or Biologics

- Item 1. Identification of Drug, Device or Biologic – identify all and whether FDA approval has been granted, if applicable.
- Item 2. Background Information – describe previous human participation, known risks, etc. as guided.
- Item 3. Source – identify the source of the item to be used.

The Research Plan

- Chapter 3
- Chapters 2 and 3
- Chapter 3

The Research Plan and the IRB Protocol Application

Part B – Protocol Format

Section X – Research Involving Drugs, Devices or Biologics

- Item 4. Preparation and Use – describe the method of preparation and use as requested.
- Item 5. Use of an Investigational Drug, Device, Biologic – If plan involves use of items not currently approved by the FDA, follow guidance. NO EXCEPTIONS.
- Item 6. FDA Requirements – follow guidance, NO EXCEPTIONS.
- Item 7. Use of Placebo – follow guidance. NO EXCEPTIONS.

The Research Plan

- Chapter 3
- Chapter 3 and Appendix
- Chapter 3 and Appendix
- Chapter 3 and Appendix

THE RESEARCH PROCESS

RESEARCH IS . . .

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

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

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