RESEARCH GUIDELINES

POSTGRADUATE DENTAL COLLEGE

JULY 2021

CONTENTS

Guidelines

All students enrolled in the Master of Science program must satisfy the Uniformed Services University's research requirements. The completion of a well-designed research effort, in conjunction with all didactic and clinical expectations of the associated residency program, is essential for graduation and award of the Master of Science in Oral Biology degree.

Each student is to work with a primary mentor of his or her choice. This mentor is commonly selected in consultation with the student's Program Director. In addition, each student must select a committee of not less than two additional faculty advisors to provide further expertise and guidance.

The research experience is intended to foster the development of master clinicians who understand basic research processes. The resultant knowledge is intended to facilitate informed assessment of the professional literature, and to support improved decision making in an evidence-based environment. Within this framework, each student is expected to: select an appropriate research topic; identify a suitable research question; conduct a thorough literature review in the area of interest; describe the methods and materials required to answer the prescribed research question; determine an appropriate sample size using accepted methods (including consultation with a statistician); complete the investigation with concurrent collection of data; apply appropriate statistical analysis/analyses to examine the data; thoroughly analyze the results; draw relevant conclusions; document the research effort in a thesis or publishable paper format as determined in consultation with the student's research committee; successfully present research results in a public forum; and complete all University documentation requirements.

Individual Service Schools will maintain information regarding research protocols, review and approval documents, progress reports, and adverse event records pertaining to human subject research. Each training site and/or program will employ the Institutional Review Board (IRB) identified by the sponsoring medical treatment facility (MTF).

Each student will provide a completed research proposal and USU Form 3202D (see Notebook Tab 2) *within one week of project approval*, which usually occurs within the first year of the residency program.

Prior to graduation, individual students will present research findings in a forum approved by their Program Directors and Service Deans. Written documentation of research must be provided in thesis format (see Notebook Tab 3) or in manuscript form as prescribed for the targeted professional publication.

An electronic version of the final thesis or manuscript must be forwarded to the Associate Dean for Dental Research before 30 June of the graduation year. The completed

document will be reviewed within the Postgraduate Dental College and forwarded to the Learning Resource Center (LRC) for archiving in electronic format. An electronically signed research approval page must accompany the completed thesis or manuscript (see Notebook Tab 4).

It is important to note that presentations and/or manuscripts based upon the student research must be approved by the applicable Service and the University prior to delivery/submission. University approval may be requested in coordination with local approval. The form for requesting University approval is appended to this document (see Notebook Tab 5).

USU FORM 3202D
DENTAL POSTGRADUATE PROJECT

VPR Site Number (VPR will assign)

Project Title:

SECTION A: STUDENT/RESIDENT INVESTIGATOR INFORMATION

Name (Last, First, MI):

Residency Program:

% Effort on this project: 0% %

Telephone: | Fax: | Email:

Address:

Type of Student/Resident | Year:

SECTION B: SIGNATURES

The following signatures attest to the validity of the above information.

Student/Resident Investigator (Date)	Research Advisor (Date)
Department Chair/Program Director (Date)	Dean (Date)

For VPR use only

In light of the above signatures, the project is approved.

USUHS Vice President for Research (Date)

SECTION C: RESEARCH ADVISOR INFORMATION

Name (Last, First, MI): (same as signature in Section B)

Telephone: | Fax: | Email:

SECTION D: PROJECT INFORMATION

1. **A copy of the research proposal must accompany this form.** The proposal must be complete yet concise and must include: 1) Title; 2) Background; 3) Objective; 4) Hypothesis or hypotheses; 5) Methods and Materials; 6) References; and 7) Budget. The document must be submitted in Word format, Times New Roman size 12, and single spaced. References may comply with style/format recommendations of any peer reviewed journal in your discipline.

2. **Is this research project related to an active research project of the advisor identified in Section C?** If yes, complete this Part C.2; if no, proceed to Part C.3. ☐ YES ☐ NO

Project Number: _____

Project Title: _____

Project Start Date: _____

Project End Date: _____

3. Anticipated Period of Performance for this Proposal Project Start: _____ Project End: _____

4. List all performance sites and indicate percentage of the work being performed at each site:

Performance Site (Should not exceed 100%)	**% of Work at Site**
USUHS (on-campus space and/or rented off-campus space)	%
Resident's Assigned Location: _____	%
Other off-site location (s): _____	%
_____	%

5. **Does this project involve any classified information?** (Contact the USU Security Office for guidance) ☐ YES ☐ NO

6. **Does this project involve research with foreign work?** (Contact the Office of Affiliations and International Affairs (OAI) for guidance) ☐ YES ☐ NO

7. **What is the funding source?**

- ☐ No Funding
- ☐ Service Dental School (Air Force, Army, Navy)
- ☐ USUHS Postgraduate Dental College
- ☐ Other

8. Does the Sponsor allow for indirect costs? ☐ YES ☐ NO ☐ N/A

9. If yes, what is the allowable rate? _____ %

10. If funded by an entity other than the Service Dental School (Air Force, Army, Navy), provide source/sources of funding:

a. _____

b. _____

c. _____

d. _____

THESIS GUIDELINES

POSTGRADUATE DENTAL COLLEGE

JULY 2021

INTRODUCTION

Research is a requirement for all students within the Postgraduate Dental College (PDC). Successful completion of the research requirement, in conjunction with the development of significant clinical and didactic expertise, is essential for graduation and award of the Master of Science in Oral Biology degree.

An expanded familiarity with research processes and procedures is intended to facilitate informed assessment of the professional literature, and to foster improved decision making in an evidence-based environment. Within this framework, each student is expected to: select an appropriate research topic; identify a suitable research question; conduct a thorough literature review in the area of interest; describe the methods and materials required to answer the prescribed research question; determine an appropriate sample size using accepted techniques; complete the investigation; collect relevant information/data; apply appropriate statistical analysis or analyses to examine the data; document the research effort in a publishable paper or thesis; and successfully defend research results in a public forum.

The information derived from PDC research efforts is intended to inform the military healthcare community as well as the broader professional and scientific communities. Individual students may choose to generate publishable papers, or to author traditional theses (in accordance with guidance from their research committees and parent Services).

Students opting to generate publishable papers should adhere to guidelines prescribed by the target publications (*e.g.*, The Journal of the American Dental Association, Journal of Dental Research, Journal of Endodontics, etc.). These guidelines are available online, and provide critical information regarding format, style, construction, length, citations, etc.

Students choosing to generate traditional theses should adhere to guidelines presented in this document.

SAFEGUARDS

The desire to safeguard personally identifiable information has yielded changes to PDC Thesis Guidelines. These changes are intended to shield critical information such as traditional “wet signatures” from public view. Toward this end, Copyright Statements are no longer required, and Thesis Approval Pages must be electronically signed.

ELEMENTS OF A THESIS

For practical purposes, a completed thesis project consists of two broad areas. These may be termed the *introductory materials* and the *body* of the document.

The introductory materials provide an overview of the thesis project. These materials include the title page, acknowledgements, dedication, abstract, and table of contents. Introductory materials also may include a list of tables, list of figures, and list of abbreviations (if indicated). Pages in this section are identified using lower case Roman numerals (ii, iii, iv, v, vi, vii, viii, ix, x, etc.). The sole exception is the title page, which is not assigned a numerical identifier.

The body of the document provides a thorough description of the research effort, as well as supporting literature. The body of the document commonly includes an introduction, literature review, research objective or objectives, methods and materials, results, discussion, conclusions, and bibliography/references. The body of the document also may include an appendix (for consent forms and other critical materials) and a brief vita. All pages in this section are identified using Arabic numerals (1, 2, 3, 4, 5, etc.), and are consecutively numbered.

INTRODUCTORY MATERIALS

Introductory materials must be arranged in the following sequence:

- **Title Page:** This represents the first page of the document. As previously noted, the title page is *not* numbered.
- **Approval Page:** This page clearly identifies members of the research committee and each member's approval of the completed research effort. To safeguard personally identifiable information (PII), individual signatures must be provided in *electronic format* (*i.e.*, e-signatures *only*). The approval page is identified using lower case Roman numeral ii.
- **Acknowledgements:** This section is used to identify contributors to the research effort. It is identified as using lower case Roman numeral iii.
- **Dedication:** This section is used to identify noteworthy individuals who were not directly involved in the research effort (*e.g.*, family, friends, supporters, etc.). This page is identified using lower case Roman numeral iv.
- **Abstract:** The abstract provides a brief overview of the research effort. The abstract should be limited to 180 words, and should include the objective or objectives of the investigation, methods and materials, results, and principal conclusions. This page is identified using lower case Roman numeral v.
- **Table of Contents:** The Table of Contents identifies major sections of the document, and the page upon which each section begins. The page or pages upon which the Table of Contents appears should be identified using sequential lower case Roman numerals (vi, vii, etc., as applicable).

- **List of Tables:** This section identifies tables within the thesis, as well as the page upon which each appears. The page number (or numbers) should represent a continuation of lower case Roman numerals from the preceding sections.
- **List of Figures:** The List of Figures identifies images, charts, and graphs which appear within the document, as well as the page upon which each appears. The page or pages displaying the List of Figures should represent a continuation of lower case Roman numerals.
- **List of Abbreviations:** This section is optional. If a List of Abbreviations is provided, pagination should follow the ongoing Roman numeral sequence.

BODY

The body of the document must be arranged in the following sequence:

- **Introduction:** The Introduction "sets the table" for what is to come. This section provides a cursory background regarding the investigation. The initial page of the Introduction is assigned Arabic numeral 1. Arabic numbers follow sequentially throughout the remainder of the document.
- **Literature Review:** This section describes research which has been accomplished in the area of interest. A thorough literature provides critical insights regarding current knowledge, and forms the foundation for the upcoming research objective or objectives. Sequential numbering continues (using Arabic numerals).
- **Research Objective or Objectives:** One or more clearly-stated research objectives are central to any research effort. Research objectives should be concise, and should clearly define the focus of the investigation. Pagination continues using sequentially-assigned Arabic numerals.
- **Methods and Materials**: The Methods and Materials section is used to describe all facets of the investigative process (*e.g.*, experimental units, processes, procedures, methods of assessment, etc.). The resultant description should allow other investigators to replicate the experimental effort. Pagination continues as previously described.
- **Results:** Information gathered as a result of the investigation is presented in this section. The information/data represents the basis for further assessment, and commonly includes raw data and associated statistical analyses. Pagination continues using sequentially-assigned Arabic numerals.
- **Discussion:** Meaningful analysis of experimental results is presented in the Discussion section. The primary researcher is expected to advance plausible explanations for observed outcomes, and to provide the rationale for such explanations. Pagination continues as previously described.

- **Conclusions:** This section contains critical assertions based upon analysis of experimental results. The Conclusions section provides definitive, "take home" messages for readers. Recommendations regarding future research efforts also may be included in this section. The uninterrupted sequence of Arabic numerals is used in pagination.
- **Appendix/Appendices:** This section may be used to provide information which is central to the research effort, yet does not appear elsewhere. Contents may include recruiting documents, consent forms, waivers, etc. Pagination should represent a continuation of lower case Arabic numerals.
- **References:** Literature cited within the body of the thesis is clearly identified within the References section. Properly-crafted citations permit readers to locate relevant information in an efficient manner. This facilitates enhanced understanding and identifies closely-aligned research efforts. Pagination continues using a continuing sequence of Arabic numerals.
- **Vita:** A brief vita may be included at the end of the document. That said, care must be taken to avoid the exposure of critical information (*e.g.*, potentially-exploitable data to include birthdates, military/civilian identifiers, etc.). Pagination is accomplished using the continuing sequence of Arabic numerals.

TYPEFACE

Electronic storage and transmission have drastically altered the methods for recording and disseminating written information. While typefaces and font sizes may be manipulated within an electronic document, this may impact pagination and negate the usefulness of reference sections (Table of Contents, List of Tables, etc.).

To prevent such difficulties, a standard sans serif typeface such as Arial or Calibri (font size 10-12) should be used. Per University guidelines, black print is required.

MARGINS, SPACING, AND INDENTATION

Left Margin: 1.5 inches

Right Margin: 1 inch

Top Margin: 1 inch

Bottom Margin: 1 inch

Spacing: The document must be double spaced

Indentation: The first line of each paragraph is to be indented 0.5 inches

PAGINATION

No punctuation of any kind should be used in page numbering.

Introductory materials should be numbered using lower case Roman numerals (ii, iii, iv, v, etc.). These numerals should be centered on the page, approximately 0.6 inches from its lower border. The title page should not display a page number, but should be counted as page i.

The body of the document should be numbered using Arabic numerals (1, 2, 3, 4, etc.). These numerals should be centered on the page, approximately 0.6 inches from the lower border. The first page of the body should be identified as 1, and all succeeding pages should be continuously numbered without restarting.

All pages in a thesis, including figures, tables, photographs, and illustrations must be numbered.

Letter suffixes such as 10a, 10b, 10c, etc. are not acceptable

No headers are permitted on any page.

FIGURE LEGENDS

Figure legends should be single-spaced, and should be placed on the same page as the accompanying image whenever possible. The descriptive text should be positioned immediately below the figure when the image is in landscape orientation, or immediately to the right of the figure when the image is in portrait orientation.

BIBLIOGRAPHY/REFERENCES

All references must follow the guidelines established by the Editorial Board of the Journal of the American Dental Association. This reference style is built into EndNote, and citations can be inserted directly into Microsoft Word from EndNote. (It is important to recognize EndNote is a reference management application available to all PDC students, and assists in the formatting process.) References are placed in the order of appearance, and are consecutively numbered.

OTHER SOURCES

For issues such as grammar and punctuation, please consult:

A Manual for Writers of Research Papers, Theses, and Dissertations, 9th Edition
Kate L. Turabian
University of Chicago Press, 2018

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2787 WINFIELD SCOTT ROAD, SUITE 220
JBSA FORT SAM HOUSTON, TEXAS 78234-7510
https://www.usuhs.edu/pdc

THESIS APPROVAL PAGE FOR MASTER OF SCIENCE IN ORAL BIOLOGY

Title of Thesis:	Enter title here
Name of Candidate:	Enter name here (First MI Last) Master of Science Degree Enter presentation/defense date here (Month day, year – example June 1, 2021)

THESIS/MANUSCRIPT APPROVED: DATE:

Electronic Signature

Enter date signed

Enter name of Supervising Professor here
ENTER DEPARTMENT AND INSTITUTIONAL AFFILIATION IN CAPITAL LETTERS
Committee Chairperson

Electronic Signature

Enter date signed

Enter name of Committee Member here
ENTER DEPARTMENT AND INSTITUTIONAL AFFILIATION IN CAPITAL LETTERS
Committee Member

Electronic Signature

Enter date signed

Enter name of Committee Member here
ENTER DEPARTMENT AND INSTITUTIONAL AFFILIATION IN CAPITAL LETTERS
Committee Member

Electronic Signature

Enter date signed

Enter name of Committee Member here
ENTER DEPARTMENT AND INSTITUTIONAL AFFILIATION IN CAPITAL LETTERS
Committee Member

Electronic Signature

Enter date signed

Enter name of Committee Member here
ENTER DEPARTMENT AND INSTITUTIONAL AFFILIATION IN CAPITAL LETTERS
Committee Member

Uniformed Services University of the Health Sciences
Manuscript/Presentation Approval or Clearance

Initiator

1. USU Principal Author
   (Last, First, Middle Initial)

2. Academic Title

3. School/Department/Center

4. Phone | 5. Email

6. Clearance ☐ Paper ☐ Article ☐ Book ☐ Presentation ☐ Other

7. Title

8. Intended Publication/Meeting

9. Required by | 10. Date of Submission

**Note: It is DoD policy that clearance of information or material shall be granted if classified areas are not jeopardized, and the author accurately portrays official policy, even if the author takes issue with that policy. Material officially representing the view or position of the University, DoD, or the Government is subject to editing or modification by the appropriate approving authority.

☐ Neither I nor any member of my family have a financial arrangement or affiliation with any corporate organization offering financial support or grant monies for this research, nor do I have a financial interest in any commercial product(s) or service(s) I will discuss in the presentation or publication.

☐ **The following statement is included in the presentation or publication:** The opinions or assertions contained herein are the private ones of the author(s) and are not to be construed as official or reflecting the view of the DoD or the USUHS.

☐ **The following items have been included in the presentation and/or publication:** Student and/or faculty USU affiliation. Examples: 1) LCDR Jane Doe, DMD, Resident, Naval Postgraduate Dental School and Uniformed Services University of the Health Sciences Postgraduate Dental College. 2) COL John Doe, DDS, Endodontics Program Director, Fort Bragg, NC and Associate Professor of Endodontics, Uniformed Services University of the Health Sciences Postgraduate Dental College. 3) USUHS logo included on title slide and/or poster

Chair/Department Head Approval**

Name (Last, First, Middle Initial)

Signature

Commander Approval** (if applicable)

Name (Last, First, Middle Initial)

School

Higher approval clearance required (for University- DoD, or US Gov't-level policy, communications systems or weapons review

Signature

Uniformed Services University of the Health Sciences
Manuscript/Presentation Approval or Clearance

Service Dean Approval**	
Name (Last, First, Middle Initial)	
School	
Higher approval clearance required (for University-, DoD, or US Gov't-level policy, communications systems or weapons review)	
Signature	
Executive Dean Approval**	
Name (Last, First, Middle Initial)	
Higher approval clearance required (for University-, DoD, or US Gov't-level policy, communications systems or weapons review)	
Signature	
Vice President for External Affairs Action	
Name (Last, First, Middle Initial)	
☐ USU Approved	☐ DoD Approval Clearance Required
☐ Submitted to DoD (Health Affairs) on	
☐ Submitted to DoD (Public Affairs) on	
☐ DoD Approved/Cleared (as written)	☐ DoD Approved/Cleared (with changes)
DoD Clearance Date	DoD Disapproval Date
Signature	

RESEARCH MILESTONES

This document provides an overview of critical steps within the research process. It is structured in a sequential/chronological manner, and is intended to assist the investigator in planning and execution of the research effort. As might be expected, successful completion of the research effort is dependent upon a team of dedicated personnel which includes the individual resident, program director, research mentor, and committee members. Hence, personnel with critical responsibilities are indicated in parentheses (see below). While active participation of the aforementioned personnel is expected, the primary responsibility for project completion rests with the resident.

Discussion of overall research objectives (Program Director or Designee)

Identification of research topic/arena (Resident)

Initial literature review (Resident)

Refinement of research topic/arena (Resident)

Identification of research mentor (Resident-Program Director)

Determination of feasibility (Resident-Mentor)

- Expertise
- Equipment/materials
- Patient population
- Financial resources
- Time

Additional refinement of research topic (Resident)

Formulation of specific research question (Resident-Mentor)

Initial draft of research proposal (Resident)

- Title
- Background
- Objective(s)
- Hypothesis
- Methods and Materials (to include study design, criteria for inclusion/exclusion, sample size, collection of data, and data analysis)
- Alignment with Operational Gap Analysis (to include Gap Designation and Sphere, see Tab 9)
- Budget
- References

Review of research proposal (Resident-Mentor)

- *Review by Associate Dean for Dental Research may be requested if significant questions or concerns exist*

Constitution of research committee (Resident-Mentor)

Review of research proposal by research committee members (Research Committee)

Finalization of research proposal (Resident-Mentor with recommendations from Research Committee)

Completion and submission of prescribed USUHS documents (Resident)

- 3202D
- Completed research proposal

Navigation of pre-investigational requirements (to include local research organizations/functions, institutional review boards, institutional animal care and use committees, offices of research and technology applications, logistics and acquisitions, etc.) (Resident)

Performance of research/data gathering (Resident)

Analysis of data (Resident)

Initial draft of manuscript (Resident)

Initial review of manuscript (Resident-Mentor)

Preliminary refinement of manuscript (Resident)

Preliminary approval of manuscript (Mentor)

Review of manuscript by research committee (Research Committee Members)

Definitive draft of manuscript (Resident-Mentor)

Research Defense/Presentation (Resident)

Approval/disapproval of completed research effort (Mentor and Research Committee)

Completion and submission of prescribed USUHS documents (Resident)

- Signed approval page (Mentor and Research Committee Members)
- Signed copyright document
- Electronic copy of completed research manuscript

Submission of manuscript for publication

RESEARCH SUPPORT GUIDE

The Uniformed Services University (USU) Office of the Vice President for Research has identified monies to support dental research. Financial awards are intended to facilitate resident research efforts and enhance the level of research conducted within the Postgraduate Dental College (PDC). As a result, eligibility will be limited to USU residents and faculty serving in supervisory roles (*i.e.*, research mentors, advisors, etc.). Management of the program will be accomplished through the Office of the Associate Dean for Dental Research, and administered via the Henry Jackson Foundation.

It must be emphasized *that individuals are not required to pursue the aforementioned monies*. If funding is available through local organizations (host facilities, clinics, hospitals, etc.), then local funding may remain the primary avenue for support.

USU-sponsored financial awards will be assigned on a competitive basis. This will require the submission of research applications (*i.e.*, proposals) which will be evaluated/scored by members of a non-partisan research committee.

If a resident or mentor is uncertain about a proposed topic's suitability for USU funding, a pre-application may be submitted. The pre-application is intended to focus the investigator's thought processes, and to assist the individual in formulating the research question, research objective(s), research plan, proposed timeline, and budget. A pre-application template is included with this document (see Tab 8).

Completed pre-applications should be forwarded to the Associate Dean for Dental Research (rodney.phoenix@usuhs.edu). Pre-applications will be evaluated by members of the Postgraduate Dental College/Uniformed Services University. Upon completion of the evaluation process, input will be provided to the author. Input will include a determination regarding the perceived competitiveness for USU funding and/or suggestions for improvement.

Please note that submission of a pre-application is not required. As previously noted, the pre-application is intended to focus the investigator's thought processes, and to permit initial evaluation by members of the Postgraduate Dental College/Uniformed Services University.

Residents and mentors who decide to forgo the pre-application process may proceed directly to proposal submission. Proposals must be submitted in Microsoft Word format. Each proposal must include the following elements:

- Applicant's Name
- Applicant's Status (resident or faculty member)
- Research Mentor's Name (if research is to be performed by resident)
- Base, Post, or Facility
- Title of Proposed Investigation
- Background

- Objective(s)
- Hypothesis or Hypotheses
- Methods and Materials (to include study design, criteria for inclusion/exclusion, sample size with accompanying power analysis/justification, data collection plan, and data analysis plan)
- Military Significance
- Institutional Relevance (identify the Gap Designation and Sphere which this research supports, see Tab 9)
- References
- Budget
- Letter of Approval signed by Program Director

Proposals must be forwarded to the Associate Dean for Dental Research (rodney.phoenix@usuhs.edu). Proposal review will be accomplished by designated members of the USUHS research community. Numerical scoring of the Background, Objective(s), Hypothesis, Methods and Materials, Military Significance, References, and Budget will be accomplished. Upon completion of numerical scoring, each reviewer will provide a recommendation regarding funding (*i.e.*, fund/do not fund/fund at modified level). Results will be submitted to the Associate Dean for Dental Research for review and applicant notification.

To ensure efficiency and accountability, each award will be maintained in an account which is linked to the research mentor and administered by the Henry Jackson Foundation. The proposed mechanism will facilitate purchase of equipment and materials, acquisition of specialized research services, rental/leasing of university-owned equipment, etc. The objective is to streamline the acquisitions process and support timely completion of approved research efforts.

Progress of funded research projects will be monitored by the Associate Dean for Dental Research. Individuals receiving USUHS sponsored research funding will be required to submit regular progress reports (every 6 months). In addition, funded researchers will be required to submit associated manuscripts upon completion of the research process. Upon review of completed manuscripts, the Associate Dean for Dental Research may recommend presentation of research results at a designated professional meeting or conference. In these instances, primary contributors (*i.e.*, residents and/or mentors) may be eligible for individual travel awards not to exceed $2,500 per person.

PRE-APPLICATION

INVESTIGATOR

RESEARCH MENTOR

LOCATION

PROJECT TITLE:

INTRODUCTION: *(i.e.*

RESEARCH OBJECTIVE(S):

RESEARCH PLAN:

TIMELINE:

BUDGET:

POSTGRADUATE

DENTAL COLLEGE

OPERATIONAL GAP ANALYSIS

(RESEARCH FOCUS)

GAP DESIGNATION	SPHERE	EXAMPLES
I. Health and Human Performance	A. Direct Relationship to Military Readiness and Deployability	1. Dental interventions impacting deployment status 2. Tobacco utilization and cessation 3. Incidence and impact of vaping 4. Other oral-systemic considerations, interactions, and/or interventions with significant military implications
	B. Oral-Systemic Considerations, Interactions, and Interventions	1. Links between oral health and cardiovascular disease, diabetes, stroke, premature birth, low birth weight, etc. 2. Genomics, microbiomics, and biofilm characterization in oral-systemic health
	C. Oral/Orofacial Pathology Detection and Treatment	1. Incidence and appearance of pathoses 2. Diagnostic aids for clinical identification of oral/orofacial pathoses 3. Surgical and non-surgical interventions for oral/orofacial pathoses 4. Management of oral/orofacial defects 5. Other oral/orofacial pathology considerations with significant military implications

GAP DESIGNATION	SPHERE	EXAMPLES
II. Prevention and Safety	A. Disease Prevention	1. Application of CAMBRA protocols for preventive purposes 2. Employment of anticariogenic materials and devices for preventive purposes 3. Other disease prevention concerns/considerations with significant military implications
	B. Patient Safety	1. Best practices 2. Clinical checklists 3. Treatment area markings 4. Tooth identification/exclusion systems (dental overlays, heads-up display systems, etc.) 5. Other patient safety concerns/considerations with significant military implications
	C. Practitioner Safety	1. Systemic effects of long-term exposure to common dental materials 2. Postural changes resulting from clinical care delivery 3. Hearing loss associated with high-frequency sound exposure 4. Impact of loupe and headlamp utilization upon vision 5. Other practitioner safety concerns/considerations with significant military implications

GAP DESIGNATION	SPHERE	EXAMPLES
III. Pain	A. Pain Management	1. Novel/emerging therapies for the management of dental pain (emerging chemistries, auricular devices and procedures, visually-mediated devices, etc.) 2. Opioid use and management 3. Opioid dependence associated with dental practice 4. Methods to counteract/mitigate the addictive properties of opioids 5. Non-opioid management of dental pain 6. Additional components and mechanisms for orofacial pain management with significant implications in dentistry and in the broader healthcare community

GAP DESIGNATION	SPHERE	EXAMPLES
IV. Materials, Devices, and Techniques	A. Restorative Materials, Techniques, and Procedures	1. Evaluation of restorative materials (polymers, ceramics, composites, hybrids, alloys, etc.) 2. Assessment and refinement of oral/orofacial restorative techniques and procedures 3. Other facets of testing, development, and refinement related to restorative materials, techniques, and procedures with significant military implications
	B. Regenerative Materials, Processes, and Procedures	1. Evaluation of relevant biologic materials (chemistries, physical characteristics, biologic potentials, etc.) 2. Biomedical engineering applications 3. Other regenerative materials, processes, and procedures with significant military implications
	C. Instrument and Device Testing	1. Assessment of dental materials and devices (handpieces, dental instruments, autoclaves, dental field units, scanners, mills, etc.) 2. Other materials and devices with significant implications within the military environment
	D. Clinical and Procedural Considerations	1. Practices and procedures impacting environmental safety 2. Other processes, procedures, techniques and materials with significant environmental implications

GAP DESIGNATION	SPHERE	EXAMPLES
V. Technology and Innovation	A. Information Management / Information Technology	1. Electronic health record (functionality, incorporation into medical record, etc.) 2. Reliable/secure communications (MEDNET, alternatives to Army SAFE site, etc.) 3. Enhanced imaging capabilities and applications 4. Enhanced analysis, planning/design, and guided surgery applications 5. Expanded CAD/CAM capabilities 6. Emerging IM/IT-based technologies 7. Other IM/IT applications with significant impact in the military environment
	B. Data Capture / Data Mining	1. Improved methods for data capture, retrieval, and analysis within the Military Health System 2. Quantification of existing and new disease 3. Clinical effectiveness of competing therapies 4. Financial and readiness ramifications of dental care 5. Other technologies and innovations with significant implications in the military healthcare environment
	C. Simulation	1. Development and/or deployment of simulation and assessment tools for use in dental training and skills development 2. Other simulation components with significant implications in the military healthcare environment
	D. Telehealth	1. Development of a viable, sustainable, and secure assessment and consultation system with telehealth applications 2. Creation, testing, and/or deployment of a remote dental treatment platform 3. Other telehealth applications with significant military applications in the military healthcare environment

BASICS OF RESEARCH DESIGN

The accompanying document provides a brief overview of the textbook *Designing a Research Project: The Basics of Biomedical Research Methodology* by Dr. Ronald G. Marks. This textbook forms the basis for a USU research design offering (available via SAKAI), and is used with the permission of the author.

These materials are to be used by USU faculty and residents only, and represent an abridged version of the aforementioned text. Initial chapters provide descriptions key concepts, critical questions, essential terminology, etc. Materials provide a well-structured, easily understandable approach to the research design process. Moreover, these materials present a common language for dental research efforts.

Remaining chapters of the text describe important considerations in protocol/proposal development. These include descriptions of data collection instruments, considerations for the optimization of research design, determination of an appropriate sample size, selection of participants, and assignment of treatments.

The overview concludes with a series of critical questions which may be used to guide the research design process.

Designing a Research Project: The Basics of Biomedical Research Methodology
Ronald G. Marks

Chapter 1
Planning a Research Project

The mental planning of any research project is at least as important as the physical collection of the data.
This book provides the beginning researcher with the basic planning steps required in any research project.
Throughout its pages, Dr. Marks provides practical examples of pitfalls which researchers must avoid. These examples include considerations such as the time required to navigate institutional review boards (IRBs), patient flow during specific times of the year (decreased during holidays), etc.
The text also provides an overview of useful terminology, information a researcher will need in discussions with statisticians, etc.

"A problem that researchers face is that many courses offered to them contain more emphasis on the computational aspects of performing statistical analyses than on design considerations. More attention should be paid to deciding which analysis should be performed than on <u>how</u> to compute it. Desktop calculators and packaged computer programs can perform all the necessary data analysis for us. Therefore, the researcher needs to concentrate on how to choose the best design and which analysis should be used on the collected data."

Key questions
1) What is the overall objective of the research project?
2) What type of data will be collected?
3) What selection process will be used in the choice of subjects for the project?
4) If various treatments are to be compared, can and should subjects receive more than one treatment?
5) How should the subjects be assigned to the various treatments?
6) How many subjects should be included in the project?
7) What will be done to put the data in a form suitable for analysis?
8) What is an appropriate statistical technique to use in data analysis?

Chapter 2
Step One: Determining the Objective and Identifying Research Components

The first step in a research project is to state its objective clearly
- You must choose a project that will be meaningful when completed and also one that can be accomplished practically
- To accomplish this, you must review the literature

The overall objective should be stated as simply as possible. Hence, you must be able to express the overall objective of your research in a concise statement.

Terminology

Experimental unit – each object studied in a research project (*e.g.*, a person, animal, bacterial culture, medical chart).

Response variable – the phenomenon (effect) being studied in the experimental unit. The response variable is also known as the dependent variable or outcome.

Universe – the entire collection of experimental units that exist (*e.g.*, all persons over age 65, all children with diabetes, all beagles with glaucoma, etc.).

Universe sample or **U-sample** – the collection of all experimental units included in a study

Population – the collection of response variable measurements for all experimental units within the universe

Population sample or **P- sample** – the response variable measurements for experimental units included in a study.

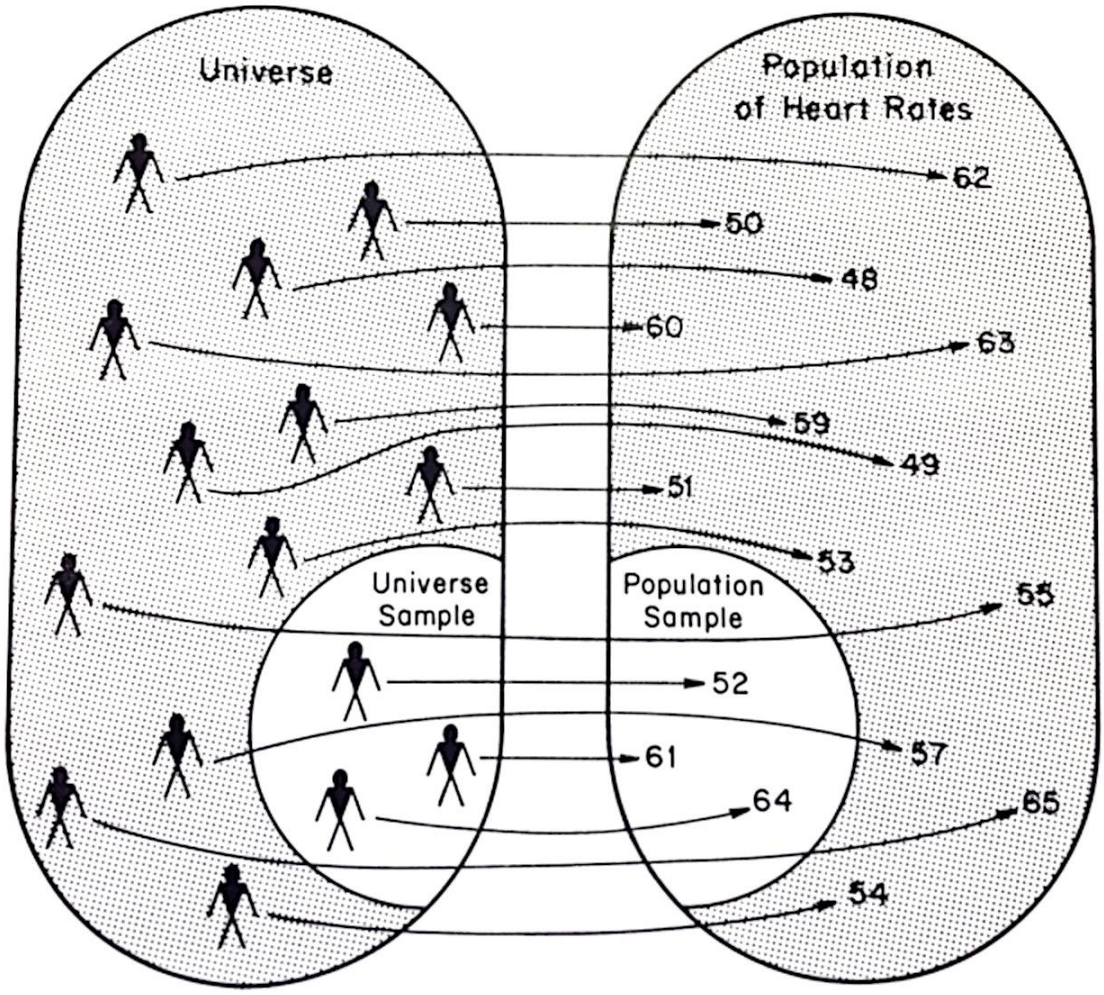

Figure 2.1 Universe and population.

Factor or **independent variable** – the treatment assigned to an experimental unit . (Each experimental factor will have at least two levels since comparison is an integral component of the research process.)
Level – the various settings of a factor assigned to an experimental unit
Experimental factor – one in which the researcher *is* responsible for assigning the levels to the experimental units.
Observational factor – one in which the researcher *is not* responsible for assigning the factor levels to the experimental units --- or even the number of levels that may occur. Hence, the researcher merely observes which level is present for an experimental study.
NOTE: Some studies contain both experimental and observational factors. As long as one experimental factor is present in the study, the study is experimental. Consequently, a study is only observational if all factors are observational.
Qualitative factor – levels are categorical in nature (such as a sealant brand, type of surgery, type of diet, or type of drug).
Quantitative factor – levels are numerical in nature (such as 5cc, 10cc, 15cc of a drug).
Extraneous factor – a factor which is not of real interest, but may affect the response variable (such as age, sex, oral hygiene, etc.). An investigator must try to control for extraneous factors in an experimental study by balancing assignment of such factors.
Prospective study – one in which the researcher is planning to measure the response variable on each experimental unit at some future time. By their very nature, all experimental studies are prospective.
Retrospective study – one in which the response variable measurements (such as disease condition) already exist, and the researcher is studying predetermined factors that may have led to the response variable measurement of interest.
NOTE: The key to whether a study is retrospective or prospective is whether the response variable measurement exists when the factor levels are observed or whether it will be obtained at some future time.
Parameter – a single number used to describe a population of response variable measurements (a global view).
Statistic – a single number used to describe a P-sample of response variable measurement (representative of a chosen study population). Computed statistics are used to make inferences about the population parameter.

Research Goal

The objective of any research project is to make some statement (inference, conclusion, decision) about a universe and the factors affecting that universe. To accomplish this goal, an investigator records measurements (response variable) on a representative group (U-sample) from the defined universe. The collection of these measurements (P-sample) then is used to reach conclusions for the complete collection of measurements (population). The investigator then relates the conclusions concerning the population to the universe of interest.

It is helpful to state the research objective in general terms as follows:

To study (or determine or evaluate) the relationship between *list of factors* and *list of response variables* on universe.

Note that the terms *effect* and *influence* are not used in statement of the research objective, because a single research project seldom can establish a cause and effect relationship.

A specific research objective should be written at the beginning of each investigation --- and the investigator should refer to it often to ensure that he/she does not become sidetracked toward another goal.

Definitions

Universe	The total collection of objects (people, animals, bacterial cultures, medical charts) that are of interest in the project
Experimental unit	Each individual object in the universe
Response variable (dependent variable)	The observation or measurement that records the state of the experimental unit for the phenomenon being studied
Population	The collection of response variable measurements on all experimental units in the universe
U-sample	The group of experimental units included in the study
P-sample	The collection of response variable measurements from the U-sample
Factor (independent variable)	A set of treatments or some other effect that is to be evaluated by the research work (type of diet, type of drug, dose of drug); or groupings of experimental units into subsets of the universe for comparison (sex, age, race, etc.)
Level of factor	Each possible setting of a factor (Diet X and Diet Y; 5cc, 10cc, 15cc of a drug; male and female)

Factors may be classified as follows:

Qualitative factor	One that has levels that are categorical (*e.g.*, type of drug, type of surgery, type of birth control, gender)
Quantitative factor	One that has numerical levels (*e.g.*, dose of drug, time spent in surgery, age)
Extraneous factor	A factor that is not of primary interest to the researcher, but may have an effect on the response variable. Such a factor may be qualitative or quantitative.

Factors also may be classified as:

Experimental factor	One in which the researcher has the responsibility for assigning the factor levels to the experimental units
Observational factor	One in which the researcher observes the level of the factor present in the experimental unit

Research projects may be described as:

Experimental study	A research project that contains at least one experimental factor
Observational study	A research project that contains only observational factors

An important distinction between types of studies is as follows:

Prospective studies	A project in which the researcher chooses the experimental units, assigns levels of the experimental factors, notes levels of the observational factors, and measures response variable at some future time
Retrospective studies	A project in which the response variable measurement already exists and the researcher is not trying to influence it. Instead, he or she is studying predetermined factors that may be related to the response variable measurements.

Types of retrospective studies include:

Case-control study	One in which the researcher chooses a group of experimental units with a particular response variable measurement (usually presence of a disease state) and a control group with a different response variable measurement (usually absence of the identified disease state) and compares these groups on their levels of a factor of interest.
Cross-sectional Survey	One in which the factor levels and response variable measurements are all assessed at the same time

Additional terms of interest include:

Parameter	A single number used to describe a population of response variable measurements
Statistic	A single number used to describe a P-sample of response variable measurements

Chapter 3
Examples Using the Needed Terminology

The author uses examples to clearly describe key terms. Examples include:
1) A study of factors related to weight loss following gastric partition surgery
2) Estimating generic substitution in Florida
3) Evaluation of the influence of SO_2 on breathing
4) Toothpaste comparison study
5) A comparison of survival times in a cancer study

The forgoing examples allow readers to assess basic research scenarios, and to identify critical aspects of these scenarios (*e.g*., independent variables, dependent variables, U-samples, P-samples, etc.). This permits improved familiarity with key terms and an improved understanding of the research process.

If the objective of a research project has been properly defined, the researcher should be able to answer the following questions:
1) What is the **universe of interest**?
2) How would you describe an **experimental unit** for this investigation?
3) What is/are the **response variable(s)** to be measured?
4) What is/are the **factor(s**) to be studied? (qualitative and quantitative)
5) What are the **levels** for each factor listed above?
6) Which factors are **experimental** and which are **observational**?
7) Are there **extraneous factors** that may affect response variable measurements?

8) Is the study **retrospective** or **prospective**?
9) Is the study **experimental**, **case-control**, or a **cross-sectional survey**?

Chapter 4
Step Two: Deciding What Type of Data to Collect

There are four types of response variables: nominal, ordinal, discrete, and continuous.

A **nominal response variable** is verbal in nature. The response simply places the experimental unit in exactly one of a number of categories.

An **ordinal response variable** is similar to a nominal response variable in that it is verbal. With ordinal response variables, however, possible responses my be ranked in some manner. (It should be noted that certain numerical response variables may be considered ordinal as well --- such as cancer staging.)
Examples of ordinal response variable include:

unemployed < manual labor < blue collar labor < white collar employment
no colic < mild colic < moderate colic < moderately severe colic < severe colic
no plaque < slight plaque < moderate plaque < severe plaque
strongly disagree < disagree < neutral < agree < strongly agree

A **discrete response variable** can assume only certain numerical values, usually integers.
Examples of discrete response variables include:

number of children a woman has had
number of publications a professor has
number of prescription drugs a person is taking at a given time

A **continuous response variable** can take on any numerical value in a specified range. It is assumed that no two experimental units have exactly the same response characteristic, and the accuracy of measurements is limited by the investigator's or instrument's ability to obtain an exact measurement. Weight, for instance, is measured on a continuum, and no two individuals have exactly the same weight. Most physiological response variables such as height, weight, blood pressure, heart rate, calcium level, and potassium level are measured on continuous scales.
Continuous response variable can be divided into two categories --- **interval** and **ratio**. However, both interval and ratio response variable are commonly treated the same way in data analysis, so we will not go into the distinction between them.

At this juncture, Dr. Marks provides an example which demonstrates the importance of selecting an appropriate response variable. In turn, he describes *measurement error*, as well as *validity*, *reliability*, *sensitivity*, and *specificity*.

According to Marks, "The **validity** of an instrument is its ability to accurately measure the phenomenon of interest, while the **reliability** of an instrument

describes its ability to produce accurate measurements when used by other researchers, or by the same researcher through multiple trials."

He adds, "**Sensitivity** of a test measure is its ability to correctly confirm the presence of a condition (such as a disease) --- thereby avoiding a false negative. **Specificity** is the test's ability to correctly diagnose the absence of a condition --- thus avoiding a false positive."

The relationship between the chosen response variable and the appropriate statistical analysis is then described. As might be expected, the choice of statistical test should be based upon the choice of research design and the type of response variable.

"Remember that you, the researcher, must accept complete responsibility for your research work and the results that are obtained. This part of your research should not be accepted blindly, even if it is carried out by an experienced statistician, because you are the one who must justify the results to your peers, and you must be able to answer questions about the choice of analysis and its interpretation."

"A common mistake made by first time researchers is to overestimate the amount of data that can be collected or the ease with which it can be collected."

If there is uncertainty regarding the ease, cost, or duration required to collect results, perform a pilot study to determine the realities of data collection.

It is essential that the researcher select the most appropriate response variable. This response variable must address the following questions:
1) What are some appropriate response variables for this research project?
2) Which response variables will satisfy the objective of this project?
3) Which response variable objectively measures the phenomenon of interest?
4) Which response variable can I collect using the available resources?
5) What is the type of each response variable --- nominal, ordinal, discrete, continuous?

It is essential that the researcher choose response variables that are *relevant to the research objective* and *practical to obtain*. In addition, the researcher must clearly define the type of each response variable --- nominal, ordinal, discrete, or continuous --- as this will impact the type of statistical analysis that is chosen.

Chapter 5
Step Three: Designing a Data Collection Form

Much of the information presented in this chapter is related to keypunch technologies. With improved availability and continued development of personal computers, recommendations have changed.

It is strongly recommended that an electronic data collection form be used. A properly designed electronic form helps the researcher organize results and minimize transcription errors.

A unique identifying name or number should be assigned to each experimental unit in the investigation. It is essential to recognize that care must be taken to ensure the protection of personal information such as personally identifiable information (PII) and protected health information (PHI).

Representative research examples are provided, and thought processes for associated data collection forms are provided. Critical components of these forms include information to be gathered, layout, etc.

Dr. Marks stresses the importance of consistency in data entry. In turn, he presents common problems with coding schemes. When designing an instrument for data collection, it is essential that the researcher consider potential changes which may impact the investigation. These include changes in technologies, alterations in accepted clinical procedures, geographic factors such as patient and/or provider availability, etc. Within the military environment, the researcher must consider subject availability related to assignment cycles, deployment, and training.

Chapter 6
Designing a Questionnaire

The author presents a list of factors which must be considered when designing a questionnaire. Important considerations include clarity, brevity, appearance, and the use of closed-ended questions. (The military services provide additional guidelines and constraints which must be considered. Considerations may include DoD permissions, service-specific permissions, IRB approvals, and consents. Researchers must determine current requirements, and must satisfy all applicable requirements.)

Examples of well-designed and poorly-designed survey instruments are provided.

All data collection forms must:
1) include an appropriate identifier for each experimental unit in the project
2) provide a mechanism to gather all required information
3) include defined categories (as appropriate) to cover the associated answers

Upon completion of each draft, a survey should be reviewed by others to ensure clarity, identify potential shortcomings, etc.

Chapter 7
Step Four: Increasing Information and Saving Resources: Repeated Measure and Block Designs

The goal of any research project is to maximize the amount of useful information obtained for a fixed amount of resources (time, money, etc.). *Repeated measures* and *blocking* (defined below) are important concepts in achievement of this goal. It is important to note that these concepts apply only to experimental/prospective studies.

Repeated measures: The concept of repeated measures involves examination of the chosen response on the *same* experimental unit under more than one factor level combination (*i.e.*, each experimental subject is exposed to each treatment).
In any experimental study, the researcher should consider using a repeated measure design. To determine the feasibility of a repeated measure design, the researcher must ask two questions:
1) Is it physically possible to use a repeated measure design?
2) If a repeated measure design is possible, will additional information be gained?

A repeated measure design is presented. Advantages of the design are provided. Subsequently, the author explains the importance of randomization in repeated measure designs. A repeated measure design in which the researcher can randomize the order of assignment of factor levels (*e.g.*, different drugs, different doses of a single drug, etc.) is termed a **changeover** or **crossover** design.

Blocking: The concept of blocking is commonly used in the agricultural sciences. Envision a piece of farmland that is divided into to 10 one-acre plots. If all plots are fertilized and watered in the same way, the yield should be similar for each plot. The 10 plots should be *homogenous* and together are deemed a **block**. If different treatment plans are used on the plots, differences in yield can be attributed to treatment differences.
Blocks on farms in different location also are assumed to have homogenous plots within a block, but between blocks (or farms) the plots are considered *heterogeneous*. As a result, the crop yield may differ between farms.
An analogy in the biomedical sciences involves litters of animals. Although most response variable measurements vary widely among animals, a litter of animals may be considered relatively homogenous. Thus, if we wished to compare the effect(s) of four different drugs on some response in rats, and if rats within a litter were considered relatively similar on the response variable in the absence of any drug, we might select four rats from each of a number of litters. Within each litter, four rats would be chosen and randomly assigned each of the four drugs (in such a way that each drug is given to exactly one rat). The difference(s) in response variable could be attributed primarily to individual drugs, and outcomes could be examined for consistent trends over all litters. It is important to recognize this type of blocking is used sparingly in biomedical research because animals (and people) differ greatly on most physiological measurements, and even family members are different enough that the assumption of homogeneity is not valid. Consequently, while the repeated measure design is very popular in biomedical research, blocking experiments are used less frequently.

Matched pairs: A matched pairs design is used when possible extraneous factors can be identified, and the pool of experimental units for the study is large enough to match on the extraneous factors (hence, the experimental units are considered equivalent). The disadvantages of such a design include the need to identify all possible extraneous factors and the need for a large enough pool of experimental units to provide the required number of matched samples.
Dental researchers commonly employ matched pairs investigations --- taking advantage of "split mouth" techniques. In these instances, each side of the mouth is considered an individual experimental unit, and competing treatments can be applied to the two sides. For instance, competing sealants can be applied to mandibular right and left quadrants, or competing restoratives may be tested in maxillary right and left second premolars.
Another form of matching is **group matching**. Instead of trying to match individuals, the researcher attempts to match group members overall on potential extraneous factors. Hence, if age and gender are considered extraneous factors, the researcher attempts to include a similar proportion of men and women, and to ensure that the men and women display similar age spreads. This type of matching is simpler than matched pairs, but is not as exact. Nevertheless, group matching is a practical alternative to matched pairs in many studies.

For clarity, complete repeated measure design and complete block design may be defined as follows:

Complete repeated measure design is used when each experimental unit receives *every* factor level combination being studied and has the response variable measured under each combination.

Complete block design is used when experimental units can be grouped homogenously into a block so that *every* factor level combination occurs an equal number of times in the block, and each experimental unit in the block receives exactly one factor level combination.

Examples of the aforementioned designs are provided within the text. It is important to be able to distinguish between the designs, because the choice of statistical analysis differs for these designs.

A primary consideration in deciding whether to use a repeated measure or blocking design is whether the experimental units provide a wide range of measurements for the response variable in the absence of any factor. (Variability is common in human and animal studies due to the distinct differences in such organisms. Consider the differences in blood pressure, heart rate, respiration rate which may be observed in human subjects.) If there is a large difference in the response variable

measurements, then it is to your advantage to use one of these designs, because it will increase the resultant information.

When considering repeated measures or blocking, the researcher must ask:
1) Can repeated measures or blocking be accomplished (*i.e.*, is this possible)?
2) If possible, will repeated measures or blocking yield additional information?
3) If repeated measures or blocking is employed, is the design considered complete or incomplete?

It must be remembered that repeated measures and blocking designs often allow the researcher to increase the to increase the amount of information obtained in an investigation without increasing the cost of the investigation.

Chapter 8
Step Five: Choosing the Participants for the Study

As noted in Chapter 2, the objective of any research projects is to make some decision about a universe and the factors to which it is exposed. To accomplish this, the researcher collects response variable measurements on a group of experimental units, then extrapolates the results to the entire population of response variable measurements. The researcher then interprets these results as they relate to the universe being observed. If the conclusion is to be valid, *the group of experimental units selected must represent the entire universe.*

A **bias** exists when the levels of an extraneous factor occur disproportionately in the U-sample. To minimize the likelihood of bias, the researcher should try to use a probability sampling scheme.

The four most common probability sampling schemes are:
1) simple random sampling
2) stratified sampling
3) cluster sampling
4) systematic sampling

Simple random sampling is the most commonly used of the four sampling procedures in biomedical research projects. A formal definition of simple random sampling is included below:

> If a U-sample of size n is drawn from a universe of size N in such a way that every possible U-sample of size n has the sample chance of being selected, that sampling procedure is called **simple random sampling.**

A common method for simple random sampling is described. This method employs a random number table, although random number generation also can be accomplished via specialized computer programs.

It is important to recognize that simple random sampling will not guarantee a random sample of experimental units from the universe, especially in the presence of extraneous factors. Stratified random sampling will provide more information than will simple random sampling when extraneous factors are present.

Stratified random sampling is used in an effort to address extraneous factors that are of no real interest in an investigation, but --- if ignored --- may influence results. The technique involves selecting a proportionate share of experimental units from each level of an extraneous factor. For a given sample size, stratified random sampling will provide more information than will simple random sampling by controlling for the extraneous factors.

Cluster sampling commonly is used to balance data collection considerations and cost considerations. Cluster sampling should be used in two types of situations:
1) when experimental units tend to occur in clusters and the expense of traveling between clusters is great
2) when a listing of all experimental units in the universe is not available

The effect of cluster sampling is to reduce the cost of measuring the response variable on an experimental unit.

Systematic sampling can be used when a complete list of all experimental units in the universe is available. This sampling scheme involves selecting at random an experimental unit from the first *k* experimental units in the listing. Then, every *k*th experimental unit following the initial selection is identified and included in the investigation.

Systematic sampling is simpler to perform than is simple random sampling. As a result, fewer errors are made in sample selection. In addition, the process requires less work than does simple random sampling. Systematic sampling also provides a more representative sample of the universe than does simple random sampling.

In the closing sections of this chapter, the author describes difficulties which may be encountered when using surveys and questionnaires. Methods to increase responses to surveys and questionnaires are provided.

Chapter 9
The Matter of Sample Size Determination

The first step in determining the sample size is to restate the research objective in terms of the appropriate population parameters (if possible). Remember that the parameter P denotes the percentage of observations that fall into a particular category of a nominal response variable, ξ denotes the median of an ordinal variable, μ denotes the mean of a numerical response variable, and σ^2 denotes the variability of a numerical response variable.

In general, a research objective always is one of two types:
1) to estimate accurately some parameter (P) or combination of parameters (P_1-P_2)
2) to test a hypothesis about a parameter or set of parameters

If the response variable is numerical and we wish to make an inference about the parameter μ or μ_1-μ_2, we must be able to provide an estimate of the variability of the response variable. This estimate σ is necessary whether our objective involves parameter estimation or hypothesis testing.

In general, the more variability present in the response variable, the more difficult it becomes to answer a particular research question. Thus, as the variability increases, the sample size must be increased to enable you to draw an inference about an entire population of response variable measurements.

Trying to determine the variability in response variable measurements can present a problem --- often we do not know beforehand how variable the measurements will be. At the very least, we should have an idea of the approximate range of the response variable. The **range** is defined as the difference between the largest and smallest possible measurements in the population. With this information, the **standard deviation** (σ) for a population can be estimated as one-fourth of the range. Hence, $\sigma \approx$ range/4.

Commonly, the objective of a research project is to estimate some parameter (*i.e.*, to predict or characterize some behavior over an entire population). In any estimation problem, the researcher must arrive at both a **point estimate** and an **interval estimate**. The point estimate is the best guess of the true value of the parameter you wish to estimate, while the interval estimate gives a measure of the accuracy of that point estimate by providing an interval that should contain the true value of the parameter of interest. It is important to note, a larger sample size yields a smaller interval estimate.

The point and interval estimates are combined to form what is called a **confidence interval**. In most instances, a 95% confidence interval is calculated. The term 95% is termed the **confidence coefficient,** and reflects our confidence that the computed interval will contain the parameter of interest. (It follows that a 99% confidence interval is wider than a 95% confidence interval, which is wider than a 90% confidence interval.)

If we choose: 1) the confidence coefficient and 2) the desired size of the interval estimate, we can compute the sample size needed to achieve those results.

The objective of a research project is to gain information, and ultimately to answer a question. In any hypothesis-testing situation, there are several steps to perform. They are:
1) Determine the null hypothesis (H_0)
2) Determine the alternative hypothesis (H_a)
3) Determine a suitable significance level and power for the statistical test
4) Choose and compute the test statistic
5) Make a conclusion

All hypotheses that we consider for H_0 are stated as some equality, while those considered for H_a are stated as an inequality. With these statements in mind:
H_0:$P_A = P_B$ describes an equality
H_a:$P_A \neq P_B$ is termed a two-tail alternative (inequality)
H_a:$P_B > P_A$ is termed a one-tail alternative (inequality)

Upon collection of the data, the appropriate test statistic is computed, and H_0 is accepted or rejected. If H_0 is rejected and it is really true, then we have committed a *Type I error*. If H_0 is accepted as true when H_a is true, then a *Type II error* has been committed.

When the decision is to reject H_0 in favor of H_a, the probability of committing a Type I error is defined as the **significance level of the statistical test** and is denoted as p or α.

The **power** of a statistical test is defined as its ability to lead to the rejection of H_0 if H_0 is really false. The power of a test may be defined as $1-\beta$, where β is the probability of a Type II error.

Before beginning a study, we would like to feel confident that both α and β will be sufficiently small, because they represent the probability of making an erroneous conclusion. Once we choose a suitable α and β, we can compute the sample size needed to test the stated hypothesis.

It is essential that the required sample size be properly determined before data collection. This increases the likelihood that results which are *statistically significant* will also be *clinically significant*.

Chapter 10
Determining the Proper Sample Size

There are several factors that must be considered when determining sample size. These include:

1) If the response variable is numerical (either discrete or continuous) the amount of variability in the response variable measurements must be measured. The more variable the measurements, the more difficult it is to achieve the research objective, and the larger the sample size required.
2) Parameter estimation and hypothesis testing are important considerations. The more accuracy that is desired in the estimated parameter, the larger the sample size required. For hypothesis testing, the smaller the difference you wish to show, the larger the required sample size will be.
3) The researcher must consider the impact of repeated measures or blocking. Repeated measure and block designs can reduce the number of experimental units required within a study.
4) One must also consider the number of factors and the number of levels of each factor.

After these questions have been answered, an appropriate mathematical formula can be used to determine the sample size. This procedure can be complicated --- and a statistician should be consulted if possible.

There are a number of interesting observations regarding sample size estimation, but two are particularly noteworthy.

1) The required sample size for a nominal response variable typically is much larger than the sample size for a numerical response variable. This is related to the fact that a single nominal response variable measurement provides much less information than does a single numerical response variable measurement. As a result, many more observations are needed to achieve the research objective if the response variable is on a nominal scale.
2) A repeated measure design typically requires far fewer experimental units than does a similar design not using repeated measures. The reason is that each experimental unit in a repeated measure design is providing much additional information. Consequently, fewer experimental units are required.

Chapter 11
Step Seven: Assigning Treatments to Study Participants

As the title implies, this chapter deals with the assignment of treatments to research subjects. Topics include rationale, randomization, blinding, etc.

The **Hawthorne effect** is a phenomenon whereby the response variable (i.e., behavior or outcome) is influenced simply because the experimental unit is aware of his/her inclusion in the study --- even if no positive or negative stimulus is provided. It is important to account for this effect to ensure that outcomes are evaluated fairly. The Hawthorne effect commonly is measured through the use of a **placebo**, which is a treatment appearing similar to the treatment of interest, but having no impact on experimental outcomes.

Appendix A
Review of Design Considerations

Before proceeding to the next phase of your research project, it is important to ensure that all decisions impacting the research design appear reasonable and acceptable. It is recommended that the researcher answer the following questions to evaluate the experimental design:

I. What is the objective of this research project?
II. Define the following terms and answer the following questions.
    A. Universe
    B. Experimental unit
    C. Response variable(s)
    D. Factors
        1. Which factors are qualitative and which are quantitative?
        2. Which factors are observational and which are experimental?
        3. Which are extraneous factors?
        4. What are the levels for each factor?
    E. Is the project prospective or retrospective?
    F. Is this study experimental, case control, or a cross-sectional survey?
III. Choosing the response variable
    A. What are some appropriate response variables for this project?
    B. Which of these response variables will allow me to achieve the objective of this project?
    C. Which of these response variables most objectively measures the phenomenon I wish to study?
    D. Which of these response variables can I realistically expect to collect with the available resources?
    E. For each response variable to be measured, what is its type: nominal, ordinal, discrete, or continuous?
IV. Will repeated measures or blocking be used in this research project?
    A. Is a repeated measure design, blocking, or matching physically possible for this project?
    B. If repeated measures or blocking is possible, will additional information be gained? (Or, is there a basic difference in the response variable between experimental units in the absence or any factors?)
    C. If repeated measures or blocking is employed, is it complete or incomplete? (Evaluate each factor separately.)
V. Choosing a sampling scheme
    A. Which type of sampling scheme (random, stratified, cluster, or systematic) is most appropriate for my research project? Should a combination of methods be used?
    B. Is it possible to employ the most appropriate sampling scheme?
    C. Will the sample of experimental units I choose using the selected sampling scheme be representative of the entire universe?
    D. What biases may be present in the sample?
    E. If biases are present, how may they affect the conclusions that will be drawn?
VI. Choosing the sample size

A. If the chosen response variable is discrete or continuous, how much variability is expected between individual response variable measurements? If this quantity is unknown, what is the range of measurements?
B. What type of inference will I make, estimation or hypothesis testing?
C. How great an effect is to be shown --- that is, how accurate an estimate, how large a difference between levels of a factor, etc.?
D. What is the confidence coefficient for my estimation inference? What are α and β for my hypothesis testing inference?
E. From a practical viewpoint, how large a sample can be taken?

VII. Choosing the randomization technique for assigning the levels of experimental factors to the experimental units

A. Identify the experimental and extraneous factors from II.D.
B. What are the potential extraneous factors for which I must control?
C. Will repeated measures or blocking be employed? In other words, will the individual experimental units or groups of homogeneous experimental units receive more than one factor level combination of the experimental factors?
D. What randomization technique shall I use to assign the levels of the experimental factors to the experimental units?
E. Should blinding (or masking) of either the experimental units or the researcher be employed?
F. Are there any moral or ethical considerations that should be weighed against the chosen randomization technique?
G. Is it necessary to obtain approval for the use of human subjects? If so, has the approval been given?