Course Title: Biostatistics and Research in Dentistry
Course Web Site: www.people.vcu.edu/~albest/DENS580/
Course Number: DENS 580
Year: 2015-2016
Semester: Fall/Spring
Credit Hours: 2

Dr. Caroline Carrico, Assistant Professor
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Office Hours/Scheduling Appointment: by email appointment

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Office Hours/Scheduling Appointment: by email appointment

Other Course Faculty:
Dr. Jack Gunsolley, JGunsolley@vcu.edu, 929-4849
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Dr. Chuck Janus, 306C Wood, CEJanus@vcu.edu, 828-0832

Course Bulletin Description
DENS 580 Biostatistics and Research Design in Dentistry. First year; both semesters; Appropriate research designs for answering research questions of importance in dentistry are examined. An array of biostatistical methods that are commonly used in the dental literature and by agencies such as the FDA to evaluate new dental products and methodologies are discussed. The course comprises a combination of lecture material on fundamental statistical information and small group seminars in which samples of articles and data from the dental literature will be discussed. One session will be devoted to a demonstration of the use of Excel for compiling a database suitable for statistical analyses. This course
provides the starting point for the student to complete the thesis requirements for the MS degree. Subsequently, each student will present his or her own research project for discussion of design and analysis issues by the entire class.

**Pre-requisites**
admission to dental school residency or permission of the instructor

**Course Purpose Statement**
The purpose of this course is to better enable residents to critically read the literature and to prepare them to design and execute their Masters thesis project.

**Course Instructional Map**

<table>
<thead>
<tr>
<th>Learning Objective</th>
<th>How Objective is Taught (specific lecture, lab exercise, clinical assignment etc.)</th>
<th>How Student Learning is Measured (for each objective)</th>
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</thead>
<tbody>
<tr>
<td>Understand the structure of various types of data sets and which analytical methods can be used to evaluate the questions asked by the dental investigator.</td>
<td>Reading assignment, lecture, and in-class discussion</td>
<td>In-class exercise</td>
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<td>Read articles in the dental literature with an understanding of the appropriateness of the study design in relationship to the hypotheses posed by the investigator. Determine if conclusions in the dental literature that are based upon utilization of appropriate study design and statistical methodologies are valid.</td>
<td>Read articles and prepare critiques</td>
<td>Grading of critiques</td>
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<tr>
<td>Be able to ask a research question of their own, design an appropriate study to answer that question, anticipate the structure of the data that will be derived, and determine which statistical tests will be used to analyze that data set.</td>
<td>In concert with their thesis advisor and committee, prepare a Thesis proposal.</td>
<td>Approved thesis proposal.</td>
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<td>To understand the language of statistics and study design in order to be able to knowledgeably work with a statistical consultant.</td>
<td>Read textbook, lecture, in-class discussion</td>
<td>Grading of critiques</td>
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<td>To prepare students for completion of the thesis requirements for the Master of Science in Dentistry. Information on thesis preparation is available on the School of Graduate Studies website <a href="http://www.vcu.edu/gradweb">http://www.vcu.edu/gradweb</a></td>
<td>In concert with their thesis advisor and committee, prepare a Thesis proposal.</td>
<td>Approved thesis proposal</td>
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</table>
Changes Made Since Last Course Offering

Updated exercises and papers. Added topics

**COURSE BOOKS & MATERIALS**

Beth Dawson, Robert Trapp *Basic and Clinical Biostatistics*
Publisher: McGraw-Hill Medical; 4 edition (April 2, 2004). Lange basic science paperback
www.people.vcu.edu/~albest/DENS580/DawsonTrapp/TableOfContents.htm

And the following dental and methodology papers: www.people.vcu.edu/~albest/DENS580/biblio.htm

**Dental Papers**

0. DaSilva, J.D., et al. Outcomes of implants and restorations placed in general dental practices: A retrospective study by the practitioners engaged in applied research (PEARL) network. 2014 JADA 145(7): 704-713.


**Methods Papers**


5. **Jones, Jarvis & Lewis** “Trials to assess equivalence ...” BMJ (1996). (and the full size [figure](#))

**COURSE SCHEDULE**

Course meeting schedule for each session are:

<table>
<thead>
<tr>
<th>Date</th>
<th>Session</th>
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<tbody>
<tr>
<td>Tuesday, August 04, 2015</td>
<td>Seminar 1: Orientation and Overview</td>
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<td>Thursday, August 06, 2015</td>
<td>Seminar 2: Study Designs in Medical Research</td>
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<tr>
<td>Tuesday, August 11, 2015</td>
<td>Seminar 3: Reading and Assessing the Literature</td>
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<td>Thursday, August 13, 2015</td>
<td>Seminar 4: Recognizing Sources of Bias in the Literature</td>
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<td>Tuesday, August 18, 2015</td>
<td>Seminar 5: Overview of Statistical Methods</td>
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<td>Thursday, August 20, 2015</td>
<td>Seminar 6: Summarizing and Displaying Continuous Data</td>
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<tr>
<td>Tuesday, August 25, 2015</td>
<td>no class (ORTHO out)</td>
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<tr>
<td>Thursday, August 27, 2015</td>
<td>Seminar 7: Summarizing and Displaying Nominal Data</td>
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<tr>
<td>Tuesday, September 01, 2015</td>
<td>Seminar 8: Estimation and confidence intervals, hypothesis testing, significance levels</td>
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<td>Thursday, September 03, 2015</td>
<td>Seminar 9: An Example of a Paper Critique</td>
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<td>Tuesday, September 08, 2015</td>
<td>Seminar 10: Paper Critiques</td>
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<td>Thursday, September 10, 2015</td>
<td>Seminar 11: Use of Humans and Animals in Research</td>
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<tr>
<td>Tuesday, September 15, 2015</td>
<td>Seminar 12: Proportions and Contingency Tables</td>
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<tr>
<td>Thursday, September 17, 2015</td>
<td>Seminar 13: Critiques: Proportions and Contingency Tables</td>
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</table>
Tuesday, September 22, 2015  Race week (no class)
Thursday, September 24, 2015  Race week (no class)
Tuesday, September 29, 2015  Seminar 14: Comparing means (t-test)
Thursday, October 01, 2015  Seminar 15: Critiques: Comparing means
Tuesday, October 06, 2015  Seminar 16: RAMS-IRB 101 Interactive Course
Thursday, October 08, 2015  Concept papers
Tuesday, October 13, 2015  Concept papers
Thursday, October 15, 2015  Concept papers
Tuesday, October 20, 2015  Concept papers
Thursday, October 22, 2015  Seminar 17: Critiques: Comparing means; Building a database
Tuesday, October 27, 2015  Seminar 18: Review of Methods and ANOVA
Thursday, October 29, 2015  No class (ORTHO interviews)
Tuesday, November 03, 2015  Seminar 19: Critiques of Papers
Thursday, November 05, 2015  Seminar 20: Critiques of Papers
Tuesday, November 10, 2015  Seminar 21: Citations and Bibliographies
Thursday, November 12, 2015  Seminar 22: Thesis and Journal Styles
Tuesday, November 17, 2015  [TBD]
Thursday, November 19, 2015  Seminar 23: Equivalence or “just as good as” Claims
Tuesday, November 24, 2015  no class (Thanksgiving)
Thursday, November 26, 2015  no class (Thanksgiving)
Tuesday, December 01, 2015  Thesis "preliminary draft" due; no class

DENS580 resumes

Tuesday, January 12, 2016  one on one meetings with Dr. Best or Dr. Carrico
Thursday, January 14, 2016  one on one meetings with Dr. Best or Dr. Carrico
Tuesday, January 19, 2016  one on one meetings with Dr. Best or Dr. Carrico
Thursday, January 21, 2016  one on one meetings with Dr. Best or Dr. Carrico
Tuesday, January 26, 2016  one on one meetings with Dr. Best or Dr. Carrico
Thursday, January 28, 2016  Seminar 24: Logistic regression
Tuesday, February 02, 2016  Seminar 25: Logistic regression paper critiques
Thursday, February 04, 2016  Seminar 26: Survival analysis
Tuesday, February 09, 2016  Seminar 27: Critique of Survival papers
Thursday, February 11, 2016  Seminar 28: Sensitivity and Specificity; Measurement error, agreement
Tuesday, February 16, 2016  Seminar 29: Meta-Analysis and Critical Reviews

last class. Thesis, including most Methods, due.

Course topics for each session are:

#### Biostatistics and Research Design in Dentistry (DENS 580)

**Time:** 12:30 (promptly) to 1:45 (or earlier).

**Location:** Perkinson 3120 (Lutz conf. room)
Seminar 1  

**Orientation and Overview**

**Handouts:**
- General Course Information
- Topic schedule (this document)
- Bibliography
- Concept papers, what's expected

**You will also need:**

Alexander Fellowship information (due December 1)
- go to: [http://www.dentistry.vcu.edu/research/funding/school/](http://www.dentistry.vcu.edu/research/funding/school/)
- download the "purpose and eligibility" and the "application"

Author guidelines for:
- *Journal of Endodontics* [www.elsevier.com/wps/find/journaldescription.cws_home/707230/authorinstructions](http://www.elsevier.com/wps/find/journaldescription.cws_home/707230/authorinstructions)
- *Pediatric Dentistry* [www.aapd.org/assets/1/7/PDInstructions.pdf](http://www.aapd.org/assets/1/7/PDInstructions.pdf)
- *Journal of Periodontology* [www.joponline.org/userimages/ContentEditor/112438816475/Instructions_to_Authors.pdf](http://www.joponline.org/userimages/ContentEditor/112438816475/Instructions_to_Authors.pdf)
- *American Journal of Orthodontics & Dentofacial Orthopedics* [www.ajodo.org/content/authorinfo](http://www.ajodo.org/content/authorinfo)

Seminar 2

**Study Designs in Medical Research**

**Reading assignment:**

Note on reading assignments: When a paper or book chapter is assigned, graduate students are expected 1) to have read the item before the class period, 2) to bring the item to class, 3) to come prepared with questions about topics that are unfamiliar or confusing, and 4) to participate in the in-class discussion of the topics.

**Handouts given out in class:**
- Study Designs

Seminar 3

**Reading and Assessing the Literature**

**Reading assignment:**

**Handouts:**
- How to Critique Papers, How to Participate in a Paper Critique
Seminar 4  
**Recognizing Sources of Bias in the Literature**

**Reading assignment:**

also see the sections beginning on page 335, “Bias related to subject selection” in Dawson-Trapp; continuing thru “Blinding” on page 340.

Seminar 5  
**Overview of Statistical Methods**

**Reading assignment:**

**Handouts:**
Re: Baumgardner, and Summary of Statistical Analysis Methods

Seminar 6  
**Summarizing and Displaying Continuous Data**

**Reading assignment:**
Chapter 3 “Summarizing data …” in Dawson-Trapp up to but not including “Summarizing nominal and ordinal data with numbers” on page 40.

**Handout:**
Descriptive Statistics for Continuous Data

Seminar 7  
**Summarizing and Displaying Nominal Data**

**Reading assignment:**
Chapter 3 “Summarizing data …” in Dawson-Trapp starting with “Summarizing nominal and ordinal data with numbers” on page 40 thru “Tables and graphs for nominal and ordinal data” on page 47. The section on “adjusting rates” can be skimmed (pages 44-46).

**Handout:**
handout

Seminar 8  
**Estimation and confidence intervals, hypothesis testing, significance levels, power**

**Reading assignment:**
Chapter 5 “Research Questions about One Group” thru section 5.4.2 in Dawson-Trapp.

**Handout:**
Research questions about one group

Seminar 9  
**An Example of a Paper Critique**

**Reading assignment:**
Faculty will stand in as “graduate students assigned to critiques a paper”. They will lead the discussion of this paper—just as you will with future papers (See “How to Critique Papers”).

Assignment:
Come prepared with at least one question regarding the paper—see “How to Participate in a Paper Critique”. Since this an “example critique”, on this occasion your participation will not be graded.

Seminar 10

Paper Critiques

Reading assignment:

Assignments:
See “How to Critique Papers"
Arasu, Dugoni, Westphal will lead a discussion of 1 (Farooq).
Ardalan, Easterly, LaRochelle will lead a discussion of 2 (West).

Seminar 11

Use of Humans and Animals in Research

Reading assignment:
The World Medical Association Declaration of Helsinki
(download from: http://www.wma.net/en/30publications/10policies/b3/ )

Assignment (due before October 14):
Complete training for biomedical researchers human subjects protection at:
http://www.research.vcu.edu/human_research/index.htm. On this page, you’ll see “Education and Required Training” and the link to "CITI Requirements":
http://www.research.vcu.edu/human_research/citi_requirements.htm
Do the "Basic Human Subjects Protection: Biomedical Research" course.
When the training is complete, you will receive a “diploma”—print out multiple copies and turn in one copy.

Seminar 12

Proportions and Contingency Tables

Reading Assignment:
Chapter 6 “Two separate groups” in Dawson-Trapp (only the sections on contingency tables)

Note: Students will sign up for their presentations beginning in two weeks

Seminar 13

Critiques: Proportions and Contingency Tables

Reading Assignment:
Paper 3 by Lindauer et al.. Paper 4 by Jackson et al.

Assignment:
Azanoush, Javdan, Lindsey will lead a discussion of 3 (Lindauer).
Holland, Sturgill, Carrico will lead a discussion of 4 (Jackson). All will participate in the discussion.

**Seminar 14**

**Comparing means (t-test)**

**Reading assignment:**
Chapter 6, “Two separate groups”, the section on comparing means

**Seminar 15**

**Critiques: Comparing means**

**Reading Assignment:**
Paper 5 by Leelataweewud et al. Paper 6 by Farik et al.

**Assignment:**
Parikh, Stoianovici, White will lead a discussion of 5 (Leelataweewud).
Arasu, Porter, Schroeder will lead a discussion of 6 (Farik).

**Seminar**

**Concept papers due, Begin Discussion of concept papers**

**Handout:**
See “Concept Papers, what’s expected”

For the next four class periods, four students will present their proposed research concepts. Each will have 18 minutes—plan on about a 12-15 minute presentation and then open it to questions, comments, suggestions from your peers for up to 5 minutes. Note that purpose of this presentation is two-fold: 1) for the presenter to get useful feedback to improve the research, and 2) for the students in the audience to gain further experience in critiquing research.

We'll need something visual to work from. Either bring 18 copies of your concept paper or have powerpoint handouts.

Presenters (starting at 12:30):

**Seminar**

**Discussion of concept papers**
Presenters (starting at 12:30):

**Seminar**

**Discussion of concept papers**
Presenters (starting at 12:30):

**Seminar**

**Discussion of concept papers**
Presenters (starting at 12:30):

**Seminar 16**

**RAMS-IRB 101 Interactive Course**

**Reading Assignment:**
Human Subject Regulations Decision Chart:
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html
Be familiar with: "Is it research on human subjects?", "Can the IRB review be expedited?", and "When/whether informed consent is obtained?"

**In the DIM classroom in the basement of the Lyons building**
Residents will practice navigating the RAMS-IRB system and will create a new submission in the RAMS-IRB training environment. Participants will also be shown where to access additional RAMS-IRB training materials

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**Seminar 17**

**Critiques: Comparing means; Building a database**

**Reading Assignment:**
Paper 7 by Norton

**Assignment:**
Ardalan, Dugoni, Westphal will lead a discussion of 7 (Norton).

**Creating an Excel database**
Reading: none. Presented by Dr. Best

**Seminar 18**

**Review of Methods and ANOVA**

**Reading assignment:** Baumgardner and Chapter 7, “...comparing three or more groups”

**Correlation and regression**

**Reading assignment:** Chapter 8, “Relationships among variables…

**Seminar 19**

**Critiques of Papers**

**Reading Assignment:**
Paper 8 by Yee and Paper 9 by Johnson

**Assignment:**
Azanoush, Easterly, LaRochelle will lead a discussion of 8 (Yee).
Lindsey, Holland, Sturgill will lead a discussion of 9 (Johnson).
All discuss

**Seminar 20**

**Critiques of Papers**

**Reading Assignment:**
Paper 10 by Gapski and Paper 11 by Lida

**Assignment:**
Javdan, Parikh, White will lead a discussion of 10 (Gapski).
Porter, Stoianovici, Karashi will lead a discussion of 11 (Phrukkanon).

**Seminar 21**

**Citations and Bibliographies**

**Reading Assignment:**
http://guides.library.vcu.edu/refworks

**Location:**
Tomkins-McCall Library Classroom 2-006

**Assignment:**

(If you have not already done so) **Install** "Refworks: Write N Cite" add-on to MSWord thru the vcu library and **set it** so that it remembers your journal's citation/bibliography style.

Optionally: Bring the laptop you'll use to write your thesis and/or Bring a thumb drive with your Thesis on it.

**Seminar 22**

**Thesis and Journal Styles**

**Reading Assignment:**

VCU School of Graduate Studies, Theses and Dissertation Manual

One of the following:

Author guidelines for: JEndo, PedDent, Jperio, or AJODO (or the journal you'll be publishing your Thesis in).

**Assignment:**

1. **Bring** a paper copy of a recent issue of your department's preferred journal, above.
2. Go to training.vcu.edu and search for online courses in Microsoft Word (or go directly to http://office.microsoft.com/en-us/word-help/). **Complete ALL the courses** with the following keywords in their title: "tables of contents" and "using styles". Find information on how to "add captions automatically as you insert tables, figures ...".
3. (If you have not already done so) Download and save the MSWord MSDThesis template used by your department.

**Seminar 23**

**Equivalence or “just as good as” Claims**

**Reading assignment (everyone):**

Jones, Jarvis & Lewis “Trials to assess equivalence …” BMJ (1996). Dr. Best will present an overview of this material. Then we discuss the following paper:

**Assignment:**

Dugoni, Javdan, LaRochelle will lead a discussion of 14 (Burns).

All discuss

**No Class**

**Chapter 1 of Thesis Due**

No discussions, just eMail me your draft thesis TO: ALBest@vcu.edu

**Assignment:**

Written literature review for research project due. (complete "Introduction" chapter; begin "Methods")

(See “Concept Papers, What’s Expected”.) What’s due is the first draft of your thesis up to and including the Introduction section (including full lit review, plus specific aims), and a perfectly formatted bibliography. You must also **begin** your methods section including at least a rough idea of how you’ll perform the study.

This document must be formatted just as your final thesis will be formatted.
End of Fall Semester Classes

Classes resume on Tuesday, 12-Jan

Consultations with Dr. Best to finalize database design, and statistical methods

12-Jan
14-Jan
19-Jan
21-Jan

No class

Sign up to finalize your research proposal. Bring your proposal, and any associated material [such as ‘scoring sheets’ or proposed excel spreadsheets]

Seminar 24

Logistic regression

Seminar 25

Logistic regression paper critiques
Ardalan, Schroeder, White will lead a discussion of 12 (Lida).
Azanoush, Westphal, Holland will lead a discussion of 13 (Cutler).

Seminar 26

Survival analysis
Reading assignment: Chapter 9 “About survival …”

Seminar 27

Critique of Survival papers
Easterly, Parikh, Porter will lead a discussion of 15 (Becker).
Schroeder, Stoianovici, Karashi will lead a discussion of 16 (Bogacki).

Seminar 28

Sensitivity and Specificity; Measurement error, agreement
Reading assignment: Chapter 12, “Measuring the accuracy of diagnostic procedures …” and Chapter 5, “Measuring agreement” in Dawson-Trapp
Assignment:
Arasu, Lindsey, Sturgill will lead a discussion of 17 (Lanning).

Seminar 29

Meta-Analysis and Critical Reviews
Reading Assignment
"Meta-Analysis" in Chapter 10 of Dawson-Trapp, starting on page 267- to 271
Assignment: (all read and be prepared to discuss)

Final Written Research Proposal due.

this is the last class
ASSIGNMENTS, EXAMS, AND GRADING

Students are required to complete the following assignment(s) and/or examination(s) in accordance with the timeframe and parameters provided below:

Prepare and present paper critiques:

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That is:

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<td>Azanoush</td>
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<tr>
<td>Dugoni</td>
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Plus, all students are required to participate in the critique sessions by asking questions regarding the methodology and scientific reliability/validity of the studies.

**Grading Scale and Criteria**

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<tr>
<td>Marginal performance</td>
<td>B</td>
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<tr>
<td>other</td>
<td>F</td>
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**Attendance & Participation**

All students are expected to attend every class session and to participate. Exceptions must be made in advance.

**University & School Policies**

All courses, students, and faculty are governed by and accountable to the following University and School policies. Students and faculty are strongly encouraged to review all policies at the beginning of each semester. Enrollment and participation in a School of Dentistry course indicates your awareness of these policies. Policies are available on the web at the two links below.

**University Policies**

[http://www.provost.vcu.edu/faculty/syllabi.html](http://www.provost.vcu.edu/faculty/syllabi.html)

1. VCU Email Policy
2. VCU Honor System: Plagiarism and Academic Integrity
3. Student Conduct in the Classroom
4. Students with Disabilities
5. Statement on Military Short-Term Training or Deployment
6. Excused Absences for Students Representing the University
7. Campus Emergency Information
8. Important Dates - VCU
9. VCU Mobile
10. Class registration required for attendance

**School of Dentistry Policies**

[https://portal.dentistry.vcu.edu/policies/category/courses](https://portal.dentistry.vcu.edu/policies/category/courses)

1. Guidelines for the Evaluation of Student Performance and Academic Status
2. Technical Standards for Dental Education Programs
3. Guidelines Governing Examinations and Laboratory Assignments
4. Tutoring Policy
5. Grade Review Process
6. Important Dates - SoD