

# CLINICAL BIOSTATISTICS / STATISTICS IN BIOMEDICAL SCIENCES

CTSC 5103S / SGS 16:115:557 (3 credits)

Wednesdays, 4:30-7:30pm

Rutgers RWJMS Research Tower, Room V14, 675 Hoes Lane West, Piscataway, NJ

Course Director: Yen-Hong Kuo, Ph.D.

Date	Week	Topic	Readings
09/04/19	1	<b><u>Overview and Descriptive Statistics</u></b> <ul style="list-style-type: none"><li>a. Application of statistics in biomedical research</li><li>b. Type of data</li><li>c. Graphic representation of data</li><li>d. Summary statistics: central tendency and dispersion</li><li>e. Introduction to R</li></ul>	Ch. 1, 2
09/11/19	2	<b><u>Probability and Probability Distributions</u></b> <ul style="list-style-type: none"><li>a. Probability</li><li>b. Conditional probability</li><li>c. Statistical methods in diagnostic medicine and screening test</li><li>d. Binomial distribution</li><li>e. Normal distribution</li></ul>	Ch. 3, 4
09/18/19	3	<b><u>Estimation</u></b> <ul style="list-style-type: none"><li>a. Sampling distribution</li><li>b. Confidence interval<ul style="list-style-type: none"><li>1) Population means</li><li>2) Population proportions</li></ul></li><li>c. Sample size estimation based on accuracy of estimation</li></ul> <p><i>Homework Assignment Due: Summary Statistics</i></p>	Ch. 5, 6
09/25/19	4	<b><u>Hypothesis Testing</u></b> <ul style="list-style-type: none"><li>a. Type I error, Type II error</li><li>b. Steps of performing hypothesis testing<ul style="list-style-type: none"><li>1) Hypothesis testing on population means</li><li>2) Hypothesis testing on population proportions</li></ul></li><li>c. Power and sample size estimation</li></ul>	Ch. 7

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Date	Week	Topic	Readings
10/02/19	5	<b><u>Analysis of Variance</u></b> a. Comparisons between and among means b. Multiple comparisons	Ch. 8
10/09/19	6	<b><u>Analysis of Categorical Data</u></b> a. Chi-square test b. Relative risk and Odds ratio c. Sample size estimation based on proportions  <i>Homework Assignment Due: Confidence interval and hypothesis testing</i>	Ch. 12 Ch. 15
10/16/19	7	<b><u>Midterm Exam</u></b>	
10/23/19	8	<b><u>Correlation and Regression</u></b> a. Correlation b. Simple linear regression	Ch. 9
10/30/19	9	<b><u>Multiple Linear Regression and Logistic Regression</u></b> a. Multiple linear regression b. Model building and diagnosis c. Logistic regression  <i>Homework Assignment Due: Sample size estimation and Analysis of Variance</i>	Ch. 10, 11
11/06/19	10	<b><u>Nonparametric Statistics</u></b> a. Sign test b. Wilcoxon sign rank test c. Wilcoxon rank sum test d. Kruskal Wallis test	Ch. 13

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Date	Week	Topic	Readings
11/13/19	11	<b><u>Survival Analysis</u></b> <ul style="list-style-type: none"><li>a. Kaplan-Meier procedure</li><li>b. Log-rank test</li><li>c. Cox proportional hazard model</li></ul>	Ch. 14
11/20/19	12	<b><u>Pharmacoepidemiology and Meta-Analysis</u></b> <ul style="list-style-type: none"><li>a. Drug utilization</li><li>b. Drug safety</li><li>c. Drug effectiveness</li></ul> <b><u>Statistical Analysis Plan in Clinical Trials</u></b> <ul style="list-style-type: none"><li>a. Study design in drug development</li><li>b. Statistical considerations<ul style="list-style-type: none"><li>1) Sample size determination</li><li>2) Endpoint definitions</li><li>3) Analyses (safety, efficacy)</li><li>4) Interim analyses</li></ul></li></ul> <p><i>Homework Assignment Due: Regression Analysis and Nonparametric Analysis</i></p>	Handouts
11/27/19	13	<b><u>Biostatistics in the Genomic Age</u></b> <ul style="list-style-type: none"><li>a. Microarray data analysis</li></ul> <p><i>Review Assigned Readings</i></p>	Handouts
12/04/19	14	<b><u>Biostatistics in the Genomic Age</u></b> <ul style="list-style-type: none"><li>a. Microarray data analysis</li></ul> <b><u>Reading the Medical Literature</u></b> <ul style="list-style-type: none"><li>a. Use of statistical analysis in medical literature</li><li>b. Misuse of statistical analysis in medical literature</li></ul>	Handouts

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Date	Week	Topic	Readings
12/11/19	15	<b><u>Final Exam</u></b>	

## **Required Textbooks:**

**Biostatistics: A Foundation for Analysis in the Health Sciences, 10<sup>th</sup> Edition (2013)** by Wayne W. Daniel, Chad L. Cross

- ISBN-10: 1118302796, ISBN-13: 978-1118302798 (Hardcover); ISBN-13: 978-1118302798 (Wiley E-text)
- Available on Amazon at:  
<https://www.amazon.com/Biostatistics-Foundation-Analysis-Probability-Statistics/dp/1118302796>
- Notes: The 11<sup>th</sup> edition (Nov. 2018, ISBN-13: 978-1119282372) is available, and can be used as required textbook.

## **Required Software:**

**R: A Language and Environment for Statistical Computing**

- FREE
- Available from <https://www.r-project.org>

## **References and Recommended Books**

**Intuitive Biostatistics: A Nonmathematical Guide to Statistical Thinking**

- Harvey Motulsky (1995, 1<sup>st</sup> Edition; 2010, 2<sup>nd</sup> Edition; 2013, 3<sup>rd</sup> Edition; 2017, 4<sup>th</sup> Edition) Oxford University Press
- ISBN-13: 978-0195086072 (1995); 978-0199730063 (2010); 978-0199946648 (2013); 978-0190643560 (2017)

**Principles of Biostatistics, 2nd Edition**

- M. Pagano & K. Gauvreau (2000) Duxbury Press (2018 reprint) Chapman and Hall/CRC;
- ISBN-10: 0534229026; ISBN-13: 978-0534229023 (2000), 978-1138593145 (2018 reprint)

**Fundamentals of Biostatistics**

- Bernard Rosner (2005, 6<sup>th</sup> Edition; 2010, 7<sup>th</sup> Edition, Duxbury Press )(2015, 8<sup>th</sup> Edition, Brooks Cole)
- ISBN-13: 978-0534418205 (2005); 978-0538733496 (2010); 978-1305268920 (2015)

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**Assignments for Evaluation:**

- 1) Homework Assignments (n=4) (40%)**
  - a. Questions based on specific lecture topics
    - i. Use R to perform analysis
    - ii. Interpretation of results
  - b. There will be no late homework assignment submission.
  
- 2) Midterm Exam (25%)**
  - a. In class exam.
  - b. There will be no early, late, or makeup midterm exam.
  
- 3) Final Exam (35%)**
  - a. In class exam.
  - b. There will be no early, late, or makeup final exam.

<b>Grade</b>	<b>Total Score (100 points)</b>
A	90.00 - 100.00
B+	84.00 – 89.99
B	75.00 - 83.99
C+	70.00 - 74.99
C	65.00 - 69.99
F	< 65.00

**Contract Information**

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