

# Department of Biomedical Informatics

Course Title: Statistical data analysis and research methods
Course Subject Code: BMI Course Number: 504
Type of Instruction: LEC Class Number: 21287

Semester: Spring 2018

#### 1. Course Information

• Date(s)/Time(s): Thursdays 9-11.30 PM

• Delivery Mode: Traditional

• Number of Credits:

• Instructors

Course director: Werner Ceusters, MD (contact: 77 Goodell street, 5<sup>th</sup> floor, on appointment:

wceusters@gmail.com)

Lecturers:

Statistics Sarah Mullin, MSc (contact: 77 Goodell street, 5<sup>th</sup> floor, on appointment: <u>sarahmul@buffalo.edu</u>)

Epidemiology Shyamashree Sinha, MD (contact: 77 Goodell street, 5<sup>th</sup> floor, on appointment:

shyamash@buffalo.edu)

All other topics Werner Ceusters, MD (contact: 77 Goodell street, 5<sup>th</sup> floor, on appointment only through

wceusters@gmail.com)

# 2. Course Description

• This course provides an introduction to research design and methods in biomedical informatics and aims to enhance the students' quantitative and qualitative research skills. The course will be surveying the formulation of research questions, the development of testable hypotheses, the selection and application of appropriate research designs and methods, data collection and analysis methods. These skills can be applied in subsequent courses and research projects as well as in the evaluation and production of research papers. The course consists of six themes: (1) the fundamentals of scientific research; (2) elements of philosophy of science, (3) quantitative research methods including statistics; clinical epidemiology, population studies and big data; (4) theoretically informed qualitative research; (5) integration of research methods in biomedical informatics; and (6) research ethics, including informed consent, and role of IRBs. The course will encompass lectures and practicums.

• Course prerequisites: none.

# 3. Student Learning Outcomes (SLO)

Course Learning Outcomes;	BMI Graduate Program Outcomes /	Instructional Method(s)	Assessment Method(s)
students will be able to:	Competencies		
1. Explain the fundamentals of	O1:The most widely used clinical and	lecture	In-class test
scientific inquiry	informatics research methods		Essay assignment
2. Articulate research questions	O2:The generation, acquisition,	Lecture	Post-lecture quiz
	modeling, representation, and	Hands-on training	
	management of evidence-based	_	
	knowledge sources for decision		
	support		
	O3:The characteristics of public health		
	data as distinguished from clinical		
	healthcare data		
3. Assess the quality of	O1:The most widely used clinical and	Lecture	In-class test
quantitative and qualitative	informatics research methods	Hands-on session	Case studies
studies	O4:Methods of data representation,		
	manipulation, storage, analysis and		
	mining in healthcare and		
	biomedical research databases		

Understand and apply the concept of hypothesis in quantitative studies	O1:The most widely used clinical and informatics research methods. O5:Technical approaches to acquiring, modeling, representing and managing healthcare and biomedical research knowledge	Lecture with case studies Hands-on session	Post-lecture quiz
5. Explain the role of causal theories in the design and interpretation of quantitative studies	O6:Research & data management methods with large clinical populations, including clinical trials O7:The essential components of clinical and biomedical data statistical analysis	Interactive lecture Analysis of case studies Hands-on session	Participation in discussion Post-lecture quiz Inferential statistics exercise (homework)
6. Understand and use statistical methods for calculating summary estimates, measures of variability and confidence intervals	O7:The essential components of clinical and biomedical data statistical analysis	Lecture Hands-on session	In-class test Case studies
7. Understand probabilities and discrete and continuous distributions	O7:The essential components of clinical and biomedical data statistical analysis	Lecture Hands-on session	Statistical exercise (homework)
8. Carry out and interpret a variety of tests of significance	O7:The essential components of clinical and biomedical data statistical analysis	Lecture Hands-on session	Statistical exercise (homework)
Understand and use power and sample size calculations	O7:The essential components of clinical and biomedical data statistical analysis	Lecture Hands-on session	Statistical exercise (homework)
10. Use theory in qualitative research 11. Explain different forms of qualitative inquiry, including interviews, focus groups and observations and understand their benefits and limitations	O1:The most widely used clinical and informatics research methods O8:Information retrieval and critical analysis skills	Lecture Discussion of paper Interactive lecture	Open-book test Participation in discussion Participation in discussion
12. Explain and use different tools for qualitative data analysis	O7:The essential components of clinical and biomedical data statistical analysis	Lecture Hands-on session	In-class test Case study (homework)
13. Judge the suitability of different statistical methods to describe research findings	O7:The essential components of clinical and biomedical data statistical analysis	Analysis of case studies	Post-lecture quiz
14. Construct a coherent research proposal that includes an abstract, introductions, literature review, research questions, ethical considerations, and methodology	O9:Ethical theories and challenges in Biomedical Informatics	Lecture Hands-on session Analysis of case studies	In-class test Case study (homework) Post-lecture quiz Role play in editorial committee

### 4. COURSE REQUIREMENTS

- Students are required to read 22 papers and electronic publications as listed in the course materials below and several chapters out of 1 book.
- Some classes will start with a pre-test to assess the student's preparedness for the class, and a post-test to assess his attention to the lecture. Students absent for these classes will receive a 0% score for these tests unless the instructor and the course director have been informed through email of the reason for absence prior to the beginning of the class. When notified of absence in due time, the instructor may propose an alternative test or assignment for that class.
- For several lectures, availability of laptop (hands-on, open-book tests) is required.
- All assignments need to be completed prior to the deadline specified in the course schedule and send electronically to <a href="wceusters@gmail.com">wceusters@gmail.com</a>. Assignments ordered by Sinha and Mullin should, in addition to be sent to wceusters@gmail.com, also be sent to <a href="shyamash@buffalo.edu">shyamash@buffalo.edu</a> and <a href="sarahmul@buffalo.edu">sarahmul@buffalo.edu</a>, respectively. The 'sent' date in the metadata header of the message through which the completed assignments will be received will be taken for assessment of in-time delivery. Whenever an assignment is delivered past the due date, a penalty of 1% of the positive final score will be applied. This

penalty will not be applied if the assignment is not delivered at all. Students unable to meet the deadline must inform the course director and instructor by email about the reason prior to reaching the deadline. An alternative assignment and/or due date can then be agreed upon.

# 5. GRADING POLICY

- Grading follows standard graduate policies (http://grad.buffalo.edu/Academics/Policies-Procedures/Grading-Procedures.html)
- Learning assessments will be graded based on rubric criteria and weighted according to the following detailed break-down. If
  the final results for all students are outside the expected range, curve grading might be used at the discretion of the course
  director.

C1	Class	Date	Instructor	Assessment	Due dates	Score weight
Late penalty assignment result   System   Syst	C1	01-Feb	Ceusters (1)	in-class test on reading		3%
C3	C2	08-Feb	Ceusters (2)	in-class application test		3%
C3				late penalty	3/15/18 9am	1%
Late penalty				assignment result		5%
C4	C3	15-Feb	Ceusters (3)			
C4         22-Feb         Ceusters (4)         participation in discussion test on pre-class readings         2%           C5         01-Mar         Ceusters (5)         late penalty         3/8/18 9am         1%           C6         08-Mar         Mullin (0.5)         assignment result         3/14/18 9am         1%           C6         08-Mar         Mullin (1)         late penalty         3/14/18 9am         1%           C7         15-Mar         Ceusters (6)         late penalty         3/28/18 9am         1%           C8         29-Mar         Sinha (1)         test on pre-class readings late penalty         4/4/18 9am         1%           C8         29-Mar         Ceusters (7)         late penalty         4/4/18 9am         1%           Assignment result         4/4/18 9am         1%         4/4/18 9am         1%           C9         05-Apr         Ceusters (7)         late penalty         4/11/18 9am         1%           Assignment result         2%         4/4/18 9am         1%           C10         12-Apr         Ceusters (8)         role identification         2%           response to reviewers         7%         7%           C11         19-Apr         Ceusters (9)         in-class open-					2/22/18 9am	
C5				assignment result		3%
C5	C4	22-Feb	Ceusters (4)	participation in discussion		2%
Mullin (0.5)   assignment result   4%				test on pre-class readings		4%
C6         08-Mar of the content of the penalty assignment result         3/14/18 9am assignment result         1% 5%           C7         15-Mar of the penalty assignment result         3/28/18 9am assignment result         1% 5%           C8         29-Mar of the penalty assignment result         4/4/18 9am assignment result         2% 1/4/18 9am assignment result           C9         05-Apr of the penalty assignment result         4/4/18 9am assignment result         1% 4%           C10         12-Apr of the penalty assignment result         4/11/18 9am assignment result         1% 4%           C11         19-Apr of the penalty assignment result         2% 1/4/18 9am assignment result         1% 2/4           C11         19-Apr of the penalty assignment result         5/2/18 9am assignment result         1% 2/4           C12         26-Apr of the penalty assignment result         5/2/18 9am assignment result         1% 2/4           C13         3-May of the penalty assignment result         5/9/18 9am assignment result         1% 2/4           C14         10-May of the penalty assignment result         5/9/18 9am assignment result         1% 2/4           EXAM of the penalty assignment result         5/9/18 9am assignment result         2% 2/4           EXAM of the penalty assignment result         5/9/18 9am assignment result         2% 2/4           EXAM of the penalty assignme	C5	01-Mar	Ceusters (5)	late penalty	3/8/18 9am	1%
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C8				assignment result		5%
C8         29-Mar         Sinha (1)         test on pre-class readings late penalty assignment result         4/4/18 9am         1%           C9         05-Apr         Ceusters (7)         late penalty assignment result         4/11/18 9am         1%           C10         12-Apr         Ceusters (8)         role identification reviewers comments response to reviewers         2%           C11         19-Apr         Ceusters (9)         in-class open-book test         7%           C12         26-Apr         Mullin (2)         late penalty assignment result         5/2/18 9am         1%           C13         3-May         Mullin (3)         late penalty assignment result         5/9/18 9am         1%           C14         10-May         Sinha (2)         test on pre-class readings post-class test         3%           EXAM         17-May         Ceusters (10)         Positives         100%           Pre-readings In-class participation Assignments participation         28%           Assignments Final exam         40%	C7	15-Mar	Ceusters (6)	late penalty	3/28/18 9am	1%
Late penalty assignment result				assignment result		5%
C9	C8	29-Mar	Sinha (1)	test on pre-class readings		2%
C9         05-Apr         Ceusters (7)         late penalty assignment result         4/11/18 9am         1%           C10         12-Apr         Ceusters (8)         role identification reviewers comments response to reviewers         2%           C11         19-Apr         Ceusters (9)         in-class open-book test         7%           C12         26-Apr         Mullin (2)         late penalty assignment result         5/2/18 9am         1%           C13         3-May         Mullin (3)         late penalty assignment result         5/9/18 9am         1%           C14         10-May         Sinha (2)         test on pre-class readings post-class test         3%           EXAM         17-May         Ceusters (10)         Positives         100%           Pre-readings In-class participation Assignments         28%           Final exam         20%				late penalty	4/4/18 9am	1%
C10				assignment result		4%
C10         12-Apr         Ceusters (8)         role identification reviewers comments response to reviewers         2%           C11         19-Apr         Ceusters (9)         in-class open-book test         7%           C12         26-Apr         Mullin (2)         late penalty assignment result         5/2/18 9am         1%           C13         3-May         Mullin (3)         late penalty assignment result         5/9/18 9am         1%           C14         10-May         Sinha (2)         test on pre-class readings post-class test         3%         3%           EXAM         17-May         Ceusters (10)         Positives         100%           Pre-readings In-class participation Assignments Final exam         28%	C9	05-Apr	Ceusters (7)	late penalty	4/11/18 9am	1%
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C11	C10	12-Apr	Ceusters (8)	role identification		2%
C11         19-Apr         Ceusters (9)         in-class open-book test         7%           C12         26-Apr         Mullin (2)         late penalty assignment result         5/2/18 9am         1%           C13         3-May         Mullin (3)         late penalty assignment result         5/9/18 9am         1%           C14         10-May         Sinha (2)         test on pre-class readings post-class test         3%           EXAM         17-May         Ceusters (10)         Positives         100%           Pre-readings In-class participation Assignments         12%           Assignments Final exam         40%		1	, ,	reviewers comments		3%
C12         26-Apr   Mullin (2)         late penalty assignment result         5/2/18 9am         1% 5/8           C13         3-May   Mullin (3)         late penalty assignment result         5/9/18 9am         1% 5/9/18 9am           C14         10-May   Sinha (2)         test on pre-class readings post-class test         3% 5/8           EXAM   17-May   Ceusters (10)         Positives         100%           Pre-readings In-class participation Assignments Final exam         40% 5/8				response to reviewers		4%
C13	C11	19-Apr	Ceusters (9)	in-class open-book test		7%
C13         3-May         Mullin (3)         late penalty assignment result         5/9/18 9am         1% 5%           C14         10-May         Sinha (2)         test on pre-class readings post-class test         3% 5%           EXAM         17-May         Ceusters (10)         Positives         100%           Pre-readings In-class participation Assignments Final exam         40%           Final exam         20%	C12	26-Apr	Mullin (2)	late penalty	5/2/18 9am	1%
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C14         10-May         Sinha (2)         test on pre-class readings post-class test         3%           EXAM         17-May         Ceusters (10)         20%           Positives         100%           Pre-readings In-class participation Assignments Final exam         28%	C13	3-May	Mullin (3)	late penalty	5/9/18 9am	1%
EXAM         17-May         Ceusters (10)         post-class test         Positives         100%           Pre-readings         12%           In-class participation         28%           Assignments         40%           Final exam         20%			. ,	assignment result		5%
EXAM         17-May         Ceusters (10)         post-class test         Positives         100%           Pre-readings         12%           In-class participation         28%           Assignments         40%           Final exam         20%	C14	10-May	Sinha (2)	test on pre-class readings		3%
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participation Assignments Final exam 20%					_	
Assignments 40% Final exam 20%						28%
Final exam 20%						40%
					C	
					Penalties	9%

Bonus score: final score = class scores + max 30% of (100% - class scores)

- Each student who wishes to participate (consent through email) receives for each class taught by Ceusters:
  - o The detailed results of his score for that class,
  - The total results of each participating student for that class, all students (including self) being represented by unique identifiers,
  - The result of a function applied to (1) its own total score for that class and (2) the total scores of the other participating students for that class.

- To obtain a bonus score, participating students must prior to May 17 send to Ceusters their assessment of which pseudonym
  was assigned to which student.
- Scoring:
  - +10% for correct assessment of your own pseudonym;
  - +10% for finding the function,
  - +10%/(part. stud.) for each other student you assess correctly;
  - -10%/(part. stud.) for each student that assesses your pseudonym correctly.

#### Final Grades:

Grade	Quality Points	Percentage
A	4.0	93.0% -100.00%
A-	3.67	90.0% - 92.9%
B+	3.33	87.0% - 89.9%
В	3.00	83.0% - 86.9%
B-	2.67	80.0% - 82.9%
C+	2.33	77.0% - 79.9%
С	2.00	73.0% - 76.9%
C-	1.67	70.0% - 72.9%
D+	1.33	67.0% - 69.9%
D	1.00	60.0% - 66.9%
F	0	59.9 or below

An interim grade of Incomplete (I) may be assigned if the student has not completed all requirements for the course. An interim grade of T' shall not be assigned to a student who did not attend the course. The default grade accompanying an interim grade of T' shall be 'U' and will be displayed on the UB record as 'IU.' The default Unsatisfactory (U) grade shall become the permanent course grade of record if the 'IU' is not changed through formal notice by the instructor upon the student's completion of the course.

Assignment of an interim 'IU' is at the discretion of the instructor. A grade of 'IU' can be assigned only if successful completion of unfulfilled course requirements can result in a final grade better than the default 'U' grade. The student should have a passing average in the requirements already completed. The instructor shall provide the student specification, in writing, of the requirements to be fulfilled.

### 6. ACADEMIC INTEGRITY

- Academic integrity is a fundamental university value. Through the honest completion of academic work, students sustain the
  integrity of the university while facilitating the university's imperative for the transmission of knowledge and culture based
  upon the generation of new and innovative ideas. See <a href="http://grad.buffalo.edu/Academics/Policies-Procedures/Academics-Integrity.html">http://grad.buffalo.edu/Academics/Policies-Procedures/Academics-Integrity.html</a>.
- Students may collaborate for the assignments in which case the submitted materials should be clearly labeled as such, with the names of all collaborating students. In case students who collaborate cannot come to a consensus for certain parts of the work, alternate solutions proposed by individual students should be clearly marked as such. Grading of individual students will take into account such alternatives.

### 7. ACCESSIBILITY RESOURCES

If you have any disability which requires reasonable accommodations to enable you to participate in this course, please contact the Office of Accessibility Resources, 25 Capen Hall, 645-2608, and also the instructor of this course .. The office will provide you with information and review appropriate arrangements for reasonable accommodations. http://www.student-affairs.buffalo.edu/ods/

#### 8. COURSE FEES

Standard UB tuition and fees. No extra costs, except for students wishing to purchase the statistics handbook.

### 9. Course Organization / Schedule

Reference: http://registrar.buffalo.edu/calendars/academic/

### C1. Feb 1 / Ceusters / Fundamentals of research: introduction / SLO 1

### Pre class reading:

John P. A. Ioannidis

Why Most Clinical Research Is Not Useful

PLoS Med 13(6): e1002049

http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002049

#### Class structure:

- a) Overview of the course with
  - a. assessment of student expectations,
  - b. preferences in examples to be addressed within the context of resp. classes
- b) In-class test on pre-class reading
- c) Discussion of the pre-reading based on
  - a. answers from (b)
  - b. worldviews relevant to research, research versus engineering, types of research

Post-class assignment: none

Assessment: in-class test (closed book) on pre-class reading (3% of positive final score)

#### C2. Feb 8 / Ceusters / Philosophy of science and ontology / SLO 1

Pre class reading: none

#### Class structure:

- a) traditional interactive lecture covering an introduction to the philosophical basis of research with a special focus on Ontological Realism
- b) application of the previous through a guided discussion on what counts as 'mental disease'
- c) in-class application test (3% of positive final score)

#### **Post-class assignment:**

Read the following paper:

Stella Regina Taquette, Maria Cecília de Souza Minayo, Adriana de Oliveira Rodrigues

The perceptions of medical researchers on qualitative methodologies

Cad. Saúde Pública, Rio de Janeiro, 31(4):722-732, 2015

http://www.scielo.br/pdf/csp/v31n4/0102-311X-csp-31-04-00722.pdf

Write a 2-page commentary on this paper (Letter size, margins 1 inch, Arial 11p, single line spacing, justified, MS Word format or RTF) discussing the extent to which the research conducted and the report thereof follow the scientific principles for qualitative research as covered in classes C1 to C5.

Deadline: March 15, 9AM.

#### **Assessment**:

- 1) <u>in-class application test</u>: students will be presented with three evolving scenarios about behaviors in some populations. Each scenario will add some more observations about the populations. Students will be asked to suggest for each scenario hypotheses about the observed behaviors and specify a research method and analysis procedure for each hypothesis. For the 2<sup>nd</sup> and 3<sup>rd</sup> scenario, they will also need to indicate which hypotheses from the previous scenario(s), if any at all, can be ruled out on the basis of the new observations (3% of total score).
- 2) Evaluation of post-class assignment:
  - a) Delivered in time
  - b) Content (5% of positive final score)

### C3. Feb 15 / Ceusters / Qualitative research methods: theory and data collection methods / SLO 10

#### Pre-class reading:

Stella Regina Taquette, Maria Cecília de Souza Minayo, Adriana de Oliveira Rodrigues

The perceptions of medical researchers on qualitative methodologies

Cad. Saúde Pública, Rio de Janeiro, 31(4):722-732, 2015

http://www.scielo.br/pdf/csp/v31n4/0102-311X-csp-31-04-00722.pdf

#### Class structure:

- a) lecture on common qualitative data collection methods (Document Review, Observation, Interview (face-to-face), Focus Group Discussion, Ethnography,...)
- b) discussion of the C2-application test in light of a)

**Post-class assignment**: open book test with multiple choice questions and open-ended motivation based on literature. Deadline: Feb 22, 9AM.

#### Assessment:

- 1) Participation in discussion (2% of positive final score)
- 2) Evaluation of post-class assessment:
  - a) Delivered in time
  - b) Content (3% of positive final score)

### C4. Feb 22 / Ceusters / Introduction to data analysis of quantitative and qualitative variables / SLO 5, 11

### **Pre-class reading:**

1. Savitri Abeyasekera

Quantitative analysis approaches to qualitative data: why, when and how?

 $\underline{https://www.reading.ac.uk/ssc/resources/QantatitativeAnalysisApproachesToQualitativeDataWhyWhenAndHow.pdf}$ 

2. John P. A. Ioannidis

Why Most Published Research Findings Are False

PLOS Medicine 2005;2(8):e124

http://robotics.cs.tamu.edu/RSS2015NegativeResults/pmed.0020124.pdf

Class structure: interactive lecture

Post-class assignment: none

#### **Assessment**:

1) pre-lecture test on readings (4% of positive final score)

2) participation in interactive lecture (2% of positive final score)

### C5. Mar 1 / Ceusters / Descriptive and elementary statistics / SLO 3, 6

# Pre-class reading:

Anthony McCluskey and Abdul Ghaaliq Lalkhen

Statistics II: Central tendency and spread of data

Continuing Education in Anaesthesia, Critical Care & Pain 2007;7(4):127-130.

http://ceaccp.oxfordjournals.org/content/7/4/127.full.pdf+html

#### Class structure:

- a) the 1<sup>st</sup> half will be a lecture covering the theories and applications of average value, median, mode, variance, standard deviation, inter-quartile range, skewness, kurtosis, histogram, box and whisker plot. (Ceusters)
- b) The 2<sup>nd</sup> half will be a guided application of the use of R for elementary and descriptive statistics (Mullin)

**Post class assignment:** what hypotheses about the evolution of reportable communicable diseases in Erie county can you derive from the data available at <a href="http://www2.erie.gov/health/sites/www2.erie.gov.health/files/uploads/pdfs/reportablediseases.pdf">http://www2.erie.gov/health/sites/www2.erie.gov.health/files/uploads/pdfs/reportablediseases.pdf</a>? Provide arguments using methods and techniques discussed in this class and demonstrate using R. Due date: March 8, 9AM.

#### Assessment:

Evaluation of post-class assignment:

- a) Delivered in time
- b) Content (4% of positive final score)

# C6. March 8/ Mullin / Statistical analysis (I) / SLO 6, 7, 8, 9

### Pre-class readings:

Streiner, David and Norman, Geoffrey

Biostatistics: Bare Essentials People's Medical Publishing House

Chapters 4, 7 and 10 (If you need probability review, refer to chapters 5 and 6.)

Accessible through UB Libraries login: <a href="http://ebookcentral.proquest.com/lib/buffalo/detail.action?docID=3386956">http://ebookcentral.proquest.com/lib/buffalo/detail.action?docID=3386956</a>

**Class structure:** Lecture plus guided group work on Discrete and Continuous Distributions, the Normal Distribution, the Central Limit Theorem, Population vs Sample, Hypothesis Testing and Confidence Intervals (Z-test, t-test, Chi-Square Test, Fisher Exact, non-parametric), Power and Sample Size Calculations for One and Two-Sample Hypothesis tests.

**Post-lecture assignment**: will address statistical problems using R and biological data and reflect what was taught in class and the reading. A rubric will be provided for each set of problems outlining what needs to be included in order to receive full credit. Due date: March 14, 9AM.

#### **Assessment:**

Evaluation of post-class assignment:

- a) Delivered in time
- b) Content (5% of positive final score)

# C7. Mar 15 / Ceusters / Clinical epidemiology (I) / SLO 4, 5, 13, 14

### Pre-class readings:

- Stuart J. Pocock, Tim C. Clayton, Gregg W. Stone, Making Sense of Statistics in Clinical Trial Reports Journal Of The American College Of Cardiology 2015;66(22): 2536–2549 http://www.sciencedirect.com/science/article/pii/S0735109715068941
- Stuart J. Pocock, Tim C. Clayton, Gregg W. Stone,
   Statistical Controversies in Reporting of Clinical Trials
   Journal Of The American College Of Cardiology 2015;66(23): 2648 2662
   http://www.sciencedirect.com/science/article/pii/S0735109715069624
- Stuart J. Pocock, Tim C. Clayton, Gregg W. Stone,
  Design of Major Randomized Trials
  Journal Of The American College Of Cardiology 2015;66(24): 2757–2766
  <a href="http://www.sciencedirect.com/science/article/pii/S0735109715071016">http://www.sciencedirect.com/science/article/pii/S0735109715071016</a>
- Stuart J. Pocock, Tim C. Clayton, Gregg W. Stone,
   Challenging Issues in Clinical Trial Design,
   Journal Of The American College Of Cardiology 2015;66(25): 2886 2898
   http://www.sciencedirect.com/science/article/pii/S0735109715071995

**Class structure**: lecture on cohort study design, clinical study design, analysis of clinical trials, randomized controlled clinical trials, sample size and power, survival analysis, missing data, Cox proportional hazard model, hazard ratio, kaplan meier, 2x2 factorial designs, cross over designs.

**Post-lecture assignment**: there will be a post-lecture open book test with exercises covering the topics in the 4 papers. Due date: March 28, 9AM.

**Assessment**: results of open book test (5% of positive final score)

### C8. Mar 29 / Sinha / Surveys and questionnaire construction for qualitative and quantitative research / SLO 3, 12, 14

### Pre class reading:

The students can read any one (or two) of the following three papers and there will be a set of five multiple choice questions and one free text question for each paper. Bonus point may be awarded to the person that reads more. (points 10+5 for each additional paper)

Brian Castellani and John Castellani.
 Data Mining: Qualitative Analysis with Health Informatics Data.

Qualitative Health Research 2003;13(7): 1005-1018. DOI: https://doi.org/10.1177/1049732303253523

- 2. Gude WT, van der Veer SN, de Keizer NF, Coiera E, Peek N.
  Optimizing Digital Health Informatics Interventions Through Unobtrusive Quantitative Process Evaluations.
  Stud Health Technol Inform. 2016;228:594-8.
  http://ebooks.iospress.nl/publication/44682
- 3. Ashish K. Jha, E. John Orav, Jie Zheng, and Arnold M. Epstein. Patients' Perception of Hospital Care in the United States N Engl J Med 2008; 359:1921-1931. http://www.nejm.org/doi/pdf/10.1056/NEJMsa0804116

**Class structure:** the 150-minute class will be divided into two sections. The first half will be a lecture with pptx presentation. The second half will be a hands on questionnaire writing session.

Post class assignment: take home case study. Due date: March 15, 9AM.

#### **Assessment**:

- 1) Quiz on pre-class readings (2% of positive final score)
- 2) Evaluation of post-class assignment:
  - a) Delivered in time
  - b) Content (4% of positive final score)

# Mar 22: NO CLASS: SPRING RECESS

# C9. Apr 5 / Ceusters / Mixed methods: Integration of quantitative and qualitative methods / SLO 11, 12, 13

#### **Pre-class reading:**

Lawrence A. Palinkas, Gregory A. Aarons, Sarah Horwitz, Patricia Chamberlain, Michael Hurlburt, John Landsverk Mixed Method Designs in Implementation Research Adm Policy Ment Health (2011) 38:44–53 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3025112/pdf/10488\_2010\_Article\_314.pdf

**Class structure**: The first part will be an interactive lecture covering the topic. The second part will consist of a guided exercise aimed at determining the best research designs to (dis)confirm hypotheses proposed for the scenarios discussed during the in-class application test of class C2.

**Post-class assignment**: build further on the guided exercise to write a research proposal for an experimental design attempting to explain the behaviors observed as discussed during the in-class application test of class C2. Deadline: April 11, 9AM

Assessment: quality and soundness of the research proposal. (4% of positive final score)

#### C10. April 12 / Ceusters / Fundamentals of research: format and content of research papers and reports / SLO14

### **Pre-class readings:**

- 1) https://www.elsevier.com/connect/11-steps-to-structuring-a-science-paper-editors-will-take-seriously
- 2) <a href="https://www.elsevier.com/connect/8-reasons-i-rejected-your-article">https://www.elsevier.com/connect/8-reasons-i-rejected-your-article</a>
- 3) https://www.elsevier.com/connect/8-reasons-i-accepted-your-article
- 4) A recently published article, suitable for a Journal Club in biomedical informatics, TBD

**Class structure**: during the first half, the class will simulate a meeting of an editorial committee which will discuss the merits of the paper and write review comments with the possibility to indicate whether or not they individually agree with the individual comments. Different roles will be assigned to the students: neutral reviewers, biased reviewers in favor of the publication, biased against the

publication. The second half will consist of all students writing together the 'response to reviewers', with the possibility to indicate whether or not they individually agree with the way the 'group as author' would accept or deny each of the individual requests for modifications.

**Assessment**: students will be scored by the instructor on the following elements:

- a) 30%: They need to identify which students were assigned what kind of reviewer role. For each correct identification they make, they will be given two points. They will lose a point for each student by whom they are correctly identified as playing the role assigned to them. They will lose 20% of the points when recognized by no one, this to ensure they play the role right. (2% of positive final score)
- b) 30%: the degree to which their reviewers' comments correspond with those of the instructor, with extra points for comments not made by the instructor, but assessed as adequate. (3% of positive final score)
- c) 40%: the degree to which their agreement to modifications made correspond with how the instructor would respond. (4% of positive final score)

# C11. April 19 / Ceusters / Research ethics; plagiarism; informed consent; IRB / SLO 14

Pre-class reading: none

Class structure: interactive lecture followed by in-class open book test on the topics covered in the lecture.

Post-class assignment: none

Assessment: scores on in-class open-book test. (7% of positive final score)

# C12. April 26 / Mullin / Statistical analysis (II) / SLO 4, 5

Pre-class readings:

Streiner, David and Norman, Geoffrey Biostatistics: Bare Essentials People's Medical Publishing House

Chapters 8, 13

Accessible through UB Libraries login: http://ebookcentral.proquest.com/lib/buffalo/detail.action?docID=3386956

Class-structure: Lecture plus guided group work on correlation, simple linear regression, one-way and two-way ANOVA

**Post-lecture assignment**: will address statistical problems using R and biological data and reflect what was taught in class and the reading. A rubric will be provided for each set of problems outlining what needs to be included in order to receive full credit. Due date: May 9, 9AM.

### **Assessment:**

Evaluation of post-class assignment:

- a) Delivered in time
- b) Content (5% of positive final score)

### C13. May 3 / Mullin /Statistical analysis (III) / SLO 5

# **Pre-class readings:**

1. Streiner, David and Norman, Geoffrey

Biostatistics: Bare Essentials People's Medical Publishing House

Chapter 14 2. Kristin L. Sainani

Statistically Speaking: Logistic Regression

PM&R 2014;6(12):1157-1162

Through UB Libraries: http://www.sciencedirect.com/science/article/pii/S1934148214014439

Class structure: Lecture plus guided group work on Multiple Regression (cont.) and Logistic Regression

**Post-lecture assignment**: will address statistical problems using R and biological data and reflect what was taught in class and the reading. A rubric will be provided for each set of problems outlining what needs to be included in order to receive full credit. Due date: May 16, 9AM.

#### **Assessment**:

Evaluation of post-class assignment:

- a) Delivered in time
- b) Content (5% of positive final score)

### C14. May 10 / Sinha / Clinical epidemiology (II) / SLO 2, 6

# **Pre Class Readings:**

The students can read any one (or two) of the following three papers and there will be a set of five multiple choice questions and one free text question for each paper. Bonus point may be awarded to the person that reads more. (points 10+5 for each additional paper)

1. M Delgado-Rodríguez and J Llorca.

Bias.

J Epidemiol Community Health 2004;58:635-641 http://jech.bmj.com/content/58/8/635.full.pdf+html

2. Stephen J Mooney, Daniel J Westreich, and Abdulrahman M El-Sayed.

Epidemiology in the era of Big Data

Epidemiology. 2015 May; 26(3): 390-394.

http://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC4385465&blobtype=pdf

3. Griffin M. Weber, Kenneth D. Mandl, Isaac S. Kohane.

Finding the Missing Link for Big Biomedical Data

JAMA. 2014;311(24):2479-2480

http://jamanetwork.com/journals/jama/fullarticle/1883026

**Class structure**: a lecture covering the topics population studies and big data, incidence, prevalence, mortality ratios, validity, reliability, sensitivity, and specificity will be followed by discussion and Applied Epidemiology MCQ quiz.

Post-class assignment: none

Assessment: results of pre-class reading tests (3% of positive final score) and end-of-class MCQ (5% of positive final score)

#### FINAL EXAM: May 17 / 9AM

The final exam will be held in the class room. It will be composed of questions and exercises covering the complete content of the course. Students may bring their laptop to the exam pre-loaded with any documentation they consider useful to consult during the text, whether or not used during the course. However, wifi services must be disabled and use of cell phones is not allowed, this to ensure that students will do the test individually.

Assessment: 20% of positive final score

### 10. Course Materials

- This course requires the following papers and electronic publications, all of which are available publicly or through the UB Libraries:
  - 1) John P. A. Ioannidis. Why Most Clinical Research Is Not Useful. PLoS Med 13(6): e1002049, http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002049
  - 2) Stella Regina Taquette, Maria Cecília de Souza Minayo, Adriana de Oliveira Rodrigues. The perceptions of medical researchers on qualitative methodologies. Cad. Saúde Pública, Rio de Janeiro, 31(4):722-732, 2015 <a href="http://www.scielo.br/pdf/csp/v31n4/0102-311X-csp-31-04-00722.pdf">http://www.scielo.br/pdf/csp/v31n4/0102-311X-csp-31-04-00722.pdf</a>
  - 3) Savitri Abeyasekera. Quantitative analysis approaches to qualitative data: why, when and how? https://www.reading.ac.uk/ssc/resources/QantatitativeAnalysisApproachesToQualitativeDataWhyWhenAndHow.pdf
  - 4) John P. A. Ioannidis. Why Most Published Research Findings Are False. PLOS Medicine 2005;2(8):e124. <a href="http://robotics.cs.tamu.edu/RSS2015NegativeResults/pmed.0020124.pdf">http://robotics.cs.tamu.edu/RSS2015NegativeResults/pmed.0020124.pdf</a>

- 5) Brian Castellani and John Castellani. Data Mining: Qualitative Analysis with Health Informatics Data. Qualitative Health Research 2003;13(7): 1005-1018. <a href="https://doi.org/10.1177/1049732303253523">https://doi.org/10.1177/1049732303253523</a>
- 6) Gude WT, van der Veer SN, de Keizer NF, Coiera E, Peek N. Optimizing Digital Health Informatics Interventions Through Unobtrusive Quantitative Process Evaluations. Stud Health Technol Inform. 2016;228:594-8. http://ebooks.iospress.nl/publication/44682
- 7) Ashish K. Jha, E. John Orav, Jie Zheng, and Arnold M. Epstein. Patients' Perception of Hospital Care in the United States. N Engl J Med 2008; 359:1921-1931. http://www.nejm.org/doi/pdf/10.1056/NEJMsa0804116
- 8) Anthony McCluskey and Abdul Ghaaliq Lalkhen. Statistics II: Central tendency and spread of data. Continuing Education in Anaesthesia, Critical Care & Pain 2007;7(4):127-130. http://ceaccp.oxfordjournals.org/content/7/4/127.full.pdf+html
- Stuart J. Pocock, Tim C. Clayton, Gregg W. Stone. Making Sense of Statistics in Clinical Trial Reports. Journal Of The American College Of Cardiology 2015;66(22): 2536–2549. http://www.sciencedirect.com/science/article/pii/S0735109715068941
- 10) Stuart J. Pocock, Tim C. Clayton, Gregg W. Stone. Statistical Controversies in Reporting of Clinical Trials. Journal Of The American College Of Cardiology 2015;66(23): 2648 – 2662. http://www.sciencedirect.com/science/article/pii/S0735109715069624
- 11) Stuart J. Pocock, Tim C. Clayton, Gregg W. Stone. Design of Major Randomized Trials. Journal Of The American College Of Cardiology 2015;66(24): 2757–2766. http://www.sciencedirect.com/science/article/pii/S0735109715071016
- 12) Challenging Issues in Clinical Trial Design. Journal Of The American College Of Cardiology 2015;66(25): 2886 2898. http://www.sciencedirect.com/science/article/pii/S0735109715071995
- 13) M Delgado-Rodríguez and J Llorca. Bias. J Epidemiol Community Health 2004;58:635-641. http://jech.bmj.com/content/58/8/635.full.pdf+html
- 14) Stephen J Mooney, Daniel J Westreich, and Abdulrahman M El-Sayed. Epidemiology in the era of Big Data. Epidemiology. 2015 May; 26(3): 390–394. <a href="http://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC4385465&blobtype=pdf">http://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC4385465&blobtype=pdf</a>
- 15) Griffin M. Weber, Kenneth D. Mandl, Isaac S. Kohane. Finding the Missing Link for Big Biomedical Data. JAMA. 2014;311(24):2479-2480. <a href="http://jamanetwork.com/journals/jama/fullarticle/1883026">http://jamanetwork.com/journals/jama/fullarticle/1883026</a>
- 16) Kristin L. Sainani. Statistically Speaking: Logistic Regression. PM&R 2014;6(12):1157–1162. http://www.sciencedirect.com/science/article/pii/S1934148214014439
- 17) Lawrence A. Palinkas, Gregory A. Aarons, Sarah Horwitz, Patricia Chamberlain, Michael Hurlburt, John Landsverk. Mixed Method Designs in Implementation Research. Adm Policy Ment Health (2011) 38:44–53. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3025112/pdf/10488\_2010\_Article\_314.pdf
- 18) https://www.elsevier.com/connect/11-steps-to-structuring-a-science-paper-editors-will-take-seriously
- 19) <a href="https://www.elsevier.com/connect/8-reasons-i-rejected-your-article">https://www.elsevier.com/connect/8-reasons-i-rejected-your-article</a>
- 20) https://www.elsevier.com/connect/8-reasons-i-accepted-your-article
- This course requires in addition the following book: Streiner, David and Norman, Geoffrey. Biostatistics: Bare Essentials. People's Medical Publishing House. Limited copies are available in the UB Library. Older versions might be found electronically on the web. We recommend purchasing.
- One more electronic article (TBD) will be used. We will make sure it is publicly accessible.

### 11. ATTENDANCE POLICY

Students are expected to attend *all* lectures and lab exercises. For religious observances, university sanctioned events, athletic commitments and family/work obligations/emergencies, absences may be granted upon request but can have an effect on the finally obtained grade (see grading policy) unless additional coursework in replacement for missed graded activities is performed. For course cancellation/emergency planning, see the university website for cancellations/delays due to weather or other unforeseen events (<a href="http://emergency.buffalo.edu/campus-weather-alerts.html">http://emergency.buffalo.edu/campus-weather-alerts.html</a>)

# 12. CLASSROOM DECORUM

Students are expected to arrive in due time for each class. Most lectures will start with a pre-lecture test to assess the student's level of preparation for the class. This test contributes to the final grading. Use of cell phones and laptops is allowed for the purposes of the class, but not for private reasons. Additional rules of conduct, when applicable, will be explained by the instructors prior to the class.

### 13. University Support Services

Students are often unaware of university support services. For example, the Center for Excellence in Writing provides support for written work, and several tutoring centers on campus provide academic success support and resources.