

Department of Biomedical Informatics

Course Title: Statistical data analysis and research methods
Course Subject Code: BMI
Course Number: 504
Type of Instruction: SEM
Class Number: 17229

Semester: Spring 2023

Version Mar 16, 2023

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1 Course Information

• Date(s)/Time(s): Thursdays Feb 2 – May 11 (Final Exam May 18), 10AM – 12.30/1PM

• Location: Remote

• Delivery Mode: Online synchronous (with availability of class-recordings afterwards)

• Number of Credits: 3

• Instructors

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

wceusters@gmail.com)

Lecturers:

Statistics Zackary Falls, PhD (contact: 77 Goodell street, 5th floor, on appointment: <u>zmfalls@buffalo.edu</u>)

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

wceusters@gmail.com)

2 <u>Course Description</u>

• This course provides a thorough introduction to research design and methods used in biomedical sciences in general and biomedical informatics in particular. Its main aim is to enhance the students' quantitative and qualitative research skills. Five themes will be covered: (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; and (5) integration of research methods in biomedical sciences, including biomedical informatics.

- Most classes in the course consists of a theoretical and practical part, either in-class, or in the form of assignments and tests. The theoretical parts are in the form of interactive lectures 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 are then applied in the practical parts most of which are components for a research proposal which students will develop for a topic in their interest, but satisfying the principles outlined below.
- At the end of the course, students should be able to apply the methods taught in subsequent courses and research projects and use them for the evaluation and production of research proposals and papers.
- Course prerequisites: none.

3 Student Learning Outcomes (SLO)

3.1 Mapping of course learning outcomes to program and institutional outcomes and competencies.

Course Learning Outcomes; students will be able to:	BMI Graduate Program Outcomes / Competencies	Instructional methods	Assessment
Explain the fundamentals of scientific inquiry	O1:The most widely used clinical and informatics research methods	Lectures: C1, C2, C3, C5, C7, C8 Readings: R1, R2, R3, R6, R8	Tests: T1, T2 Assignments: A2, A3 Final exam
2. Articulate research questions	O2:The generation, acquisition, modeling, representation, and management of evidence-based knowledge sources for decision support O3:The characteristics of public health data as distinguished from clinical healthcare data	Lectures: C1, C2, C3, C5 Discussion: C4	Assignments: A1 Tests: T2 Final exam
3. Assess the quality of quantitative and qualitative studies	O1:The most widely used clinical and informatics research methods O4:Methods of data representation, manipulation, storage, analysis and mining in healthcare and biomedical research databases	Lectures: C3, C5, C6, C12 Discussion: C4 Guided exercise: C13	Assignments: A6
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	Lectures: C2, C7, C8, C12 Discussion: C4	Assignments: A2, A3, A6 Final exam

5. Explain the role of causal theories in the design and interpretation of quantitative studies6. Understand and use statistical	O6:Research & data management methods with large clinical populations, including clinical trials O7:The essential components of clinical and biomedical data statistical analysis O7:The essential components of	Lectures: C2, C5, C7, C8, C12 Discussion: C4 Guided exercise: C5	Assignments: A2, A3, A6 Final exam
methods for calculating summary estimates, measures of variability and confidence intervals	clinical and biomedical data statistical analysis	Lectures: C5, C10, C11	Assignment: A5 Test: T3 Final exam
7. Understand probabilities and discrete and continuous distributions	O7:The essential components of clinical and biomedical data statistical analysis	Lectures: C3, C9, C10, C11	Tests: T3 Assignment: A5 Final exam
8. Carry out and interpret a variety of tests of significance	O7:The essential components of clinical and biomedical data statistical analysis	Lectures: C3, C9, C11	Assignment: A5 Final exam
9. Understand and use power and sample size calculations	O7:The essential components of clinical and biomedical data statistical analysis	Lectures: C3, C11	Assignment: A5 Final exam
10. Use theory in qualitative research	O1:The most widely used clinical and informatics research methods	Lectures: C2, C6, C7, C8	Assignments: A2, A3, A6
11. Explain different forms of qualitative inquiry, including interviews, focus groups and observations and understand their benefits and limitations	O8:Information retrieval and critical analysis skills	Lectures: C6, C7	Assignments: A2, A6 Final exam
12. Explain and use different tools for qualitative data analysis	O7:The essential components of clinical and biomedical data statistical analysis	Lectures: C6, C7	Assignment: A6
13. Judge the suitability of different statistical methods to describe research findings	O7:The essential components of clinical and biomedical data statistical analysis	Lectures: C9, C10, C11	Assignment: A5 Final exam
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	Lectures: C1, C2, C3, C5, C6, C7, C12 Discussion: C4 Guided exercise: C13	Assignment: A6
15. Present and defend a research proposal in public	O7:The essential components of clinical and biomedical data statistical analysis	Lectures: C1, C2, C5, C6, C8, C10, C11, C12 Discussion: C4	Assignments: A7, A8
16. Reflect critically on the extent to which this course contributed to an increase in the skills and competencies you deem important for your future career	O8:Information retrieval and critical analysis skills		Final exam

3.2 Mapping of course learning outcomes to institutional outcomes and competencies.

Applicable institutional outcomes	Instructional methods	Assessment
UB1. Demonstrate domain expertise, including critical	Lectures: C1, C2, C3, C5, C6, C7,	Tests: T1, T2, T3
reasoning and analysis.	C8, C9, C10, C11, C12	Assignments: A1-A8
	Readings: R1-R11	Final exam
UB2. Apply effective communication, information,		Assignments: A6, A7
and digital literacy skills.		Final Exam
UB3. Demonstrate ethical and professional	Discussions: C4	Assignment: A8
responsibility and act according to the norms of	Guided exercises: C5, C13	
the chosen discipline.		

UB5. Collaborate positively with others to achieve a	Discussions: C4	
common purpose.	Guided exercises: C5, C13	
UB6. Assess, articulate, and acknowledge personal		Final exam
skills, abilities and growth areas.		

4 <u>Course Requirements</u>

4.1 On-line teaching and participation

- All classes will be on-line in real-time using Zoom. Students must register once in advance for all meetings using the link:
 <u>https://buffalo.zoom.us/meeting/register/tJYpduqrpzopHtRgjEul0PwAI39k_u6sLpP-</u>
 . After registering, students will receive a confirmation email containing information about joining the meetings. Attendance is restricted to students using their UB Zoom-account.
- Students are prohibited from sharing the registration link and subsequent meeting link, and doing so could lead to academic misconduct charges.
- Students must logon in time. Cameras must be on, and clearly show faces. Adjust lighting conditions of the room when needed. Microphones must be muted at login time. When the instructor asks a question, students wishing or asked to respond must unmute, and mute once ordered to do so or after finished speaking.
- If for whatever reason during the course the link will not work, or an ongoing class is interrupted either because of a failure on the side of Zoom or of the infrastructure of the instructor (interruption of power, internet access, ...), students need to stay on-line and wait for instructions over email while the instructor works out an alternative (Skype, Google chat, ...).
- Recordings of the classes will be made available.
- Students must attend all classes and must participate in class discussions. See attendance policy regulations on page 10 for exceptions.

4.2 Course materials

This course requires the following papers and electronic publications, all of which are available publicly or through the UB Libraries: (links to the papers are provided in the detailed class descriptions starting page 6):

- R1. Shortliffe, E.H., *The organization and content of informatics doctoral dissertations*. J Am Med Inform Assoc, 2016. **23**(4): p. 840-3.
- R2. Wagensberg, J., On the Existence and Uniqueness of the Scientific Method. Biol Theory, 2014. 9(3): p. 331-346.
- R3. Ioannidis, J.P., Why most published research findings are false. PLoS Med, 2005. 2(8): p. e124.
- R4. Abbasi, K., Covid-19: politicisation, "corruption," and suppression of science. BMJ, 2020. 371: p. m4425.
- R5. Ioannidis, J.P., Why Most Clinical Research Is Not Useful. PLoS Med, 2016. 13(6): p. e1002049.
- R6. Ozonoff, D.M. and P. Grandjean, What is useful research? The good, the bad, and the stable. Environ Health, 2020. 19(1): p. 2.
- R7. Delgado-Rodriguez, M. and J. Llorca, *Bias*. J Epidemiol Community Health, 2004. **58**(8): p. 635-41.
- R8. Sudheesh, K., D.R. Duggappa, and S.S. Nethra, *How to write a research proposal?* Indian journal of anaesthesia, 2016. **60**(9): p. 631-634.
- R9. Palinkas, L.A., et al., Mixed method designs in implementation research. Adm Policy Ment Health, 2011. 38(1): p. 44-53.
- R10. Almoznino, G., et al., *The Dental, Oral, Medical Epidemiological (DOME) Study: Protocol and Study Methods.* Methods Inf Med, 2020. **59**(4-05): p. 119-130.
- R11. McCluskey, A. and A.G. Lalkhen, *Statistics II: Central tendency and spread of data*. Continuing Education in Anaesthesia Critical Care & Pain, 2007. **7**(4): p. 127-130.
- R12. Cohen, H.W., P values: use and misuse in medical literature. Am J Hypertens, 2011. 24(1): p. 18-23.
- R13. Norman, G. and D. Streiner, *Biostatistics : The Bare Essentials*. 2014, Shelton, UNITED STATES: People's Medical Publishing House.
- R14. Mårtensson, P., et al., Evaluating research: A multidisciplinary approach to assessing research practice and quality. Research Policy, 2016. **45**(3): p. 593-603.

4.3 Tests and assignments

- Some classes will start with a test to assess the student's preparedness for the class. 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 about a valid reason for absence prior to the beginning of the class. When notified of absence in due time, the instructor may but is not required propose an alternative test or assignment for that class.
- All assignments except A8 need to be completed and uploaded to UB Learns as a Microsoft Word document prior to the deadline specified in the course schedule. **Google doc links or any other link to a cloud server are not allowed.** The filename should be formatted as this: BMI504-[number of the assignment]-[your UBIT name]. For example, if the course director were a student: "BMI504-A1-ceusters.docx" would be the filename for the first assignment.
- The main assignment is A6, a fully worked out proposal for a scientific research project to be built according to precise specifications given during the course. Parts of this proposal are the subject of separate assignments A1, A2, A3 and A4. This approach gives the students the opportunity to receive feedback on these components so that they can be improved for inclusion

in the final version. Grades received for these assignments do not count towards the final grade, but are to be seen as an indication of how that part of the proposal would be assessed were it included as such in the final proposal. There is thus no requirement to do assignments A1, A2, A3, and A4, but when they are not done in due time, i.e. prior to the due date, no intermediate feedback on the respective parts will be provided. Not receiving feedback on overdue assignments may of course have a negative effect on the overall score of A6.

• When assignment A5 is not delivered in time, a penalty of 1% of the positive final score will be applied for every 24 hours of delay. When this assignment is not delivered at all, the penalty will be equal to the % for which the assignment counts towards the final grade.

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.

Class	Date	Instructor	Pre-class	Assessments	Due dates	Final Score
			required readings			weight
C1	02-Feb	Ceusters (1)	R1	Post-class assignment A0	Feb 9 – 10am	
C2	09-Feb	Ceusters (2)	R2			
C3	16-Feb	Ceusters (3)	R3	In-class closed book test T1		2%
C4	23-Feb	Ceusters (4)	R4, R5, R6	Post-class assignment A1	Feb 27 - noon	3%
C5	02-Mar	Ceusters (5)	R7	In-class closed book test T2		3%
C6	09-Mar	Ceusters (6)	R8			
C7	16-Mar	Ceusters (7)	R9	Post-class assignment A2	March 27 - noon	3%
C8	30-Mar	Ceusters (8)	R10	Post-class assignment A3	April 3 - noon	3%
C9	06-Apr	Ceusters (9)		Post-class assignment A4	April 10 - noon	3%
C10	13-Apr	Ceusters (10)	R11, R12	In-class closed book test T3		3%
C11	20-Apr	Falls (1)	R13	Post-class assignment A5	April 24 - noon	5%
C12	27-Apr	Ceusters (11)				
C13	04 May	Ceusters (12)	R14	Post-class assignments A6,	May 10 – noon	30%
				A7		
C14	11-May	Ceusters (13)		In-class presentation A8		15%
EXAM	18-May	Ceusters (14)		In-class open-book exam		30%
TOTAL						100%

Scoring per student learning outcomes and assessments

Class		C1		C2		C3			C4		C5		C6		C7	C8	C9		C10		C11	C12		C13		C14	EXAM	Coverage
Readings	R1		R2		R3		R4	R5		R6		R7		R8				R9		R10			R11					
Tests						T1					T2								T3									
Assignments									A1						A2	A3	A4				A5			A6	A7	A8		
SLO1	10%	10%	20%		10%					10%	20%				10%	10%												100%
SLO2	5%		5%	5%		70%		10%		5%																		100%
SLO3						10%		10%		5%	10%		5%									15%	15%	30%				100%
SLO4			10%	10%										5%	30%	30%						10%						100%
SLO5				10%				10%		5%	25%				10%	25%						15%						100%
SLO6					10%						55%							10%	20%	5%								100%
SLO7					5%												40%	30%	20%	5%								100%
SLO8					5%												40%			5%	50%							100%
SLO9					20%	75%														5%								100%
SLO10			5%	10%									10%	20%	25%	30%												100%
SLO11													70%	10%	20%													100%
SLO12													80%		20%													100%
SLO13					5%												20%	5%	20%	5%	45%							100%
SLO14	5%	20%	5%	5%		15%		5%	5%	5%		15%		5%								10%	5%					100%
SLO15	10%	5%	5%				5%			5%		5%				20%			20%		10%	10%	5%					100%
SLO16		100%																										100%
Material																												
contribution to	30%	135%	50%	40%	55%	170%	5%	35%	10%	35%	110%	20%	165%	40%	115%	115%	100%	45%	80%	25%	105%	60%	25%	30%				
SLOs																												
Class																												
importance		10%		6%		14%			3%		9%		12%		10%	7%	6%		8%		8%	4%		3%				100%
ratio Asssessment																												
Asssessment contribution to			l			2%			3%		3%				3%	3%	3%		3%		5%			25%	E9/	15%	30%	100%
final score						270			370		370				370	3%	3%		370		3%			23%	3%	15%	30%	100%
mai score			Ь				Ь—			L				L				L		L		L					-	

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 'I' shall not be assigned to a student who did not attend the course. The default grade accompanying an interim grade of 'I' 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 COURSE FEES

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

7 Course Organization / Schedule

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

C1. Feb 2 / Ceusters / Course introduction – Introduction to research and research proposals

Required reading pre-class:

R1 Shortliffe, E.H., *The organization and content of informatics doctoral dissertations*. J Am Med Inform Assoc, 2016. 23(4): p. 840-3.

https://academic.oup.com/jamia/article/23/4/840/2201488 [1]

Class structure:

- a) Participant and instructor introduction
- b) Course introduction, housekeeping rules, expectations, course project work
- c) Traditional lecture on the structure of research proposals

Post-class assignments:

- a) Required reading
 - Wagensberg, J., On the Existence and Uniqueness of the Scientific Method. Biol Theory, 2014. 9(3): p. 331-346. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4131153/pdf/13752_2014_Article_166.pdf [2]
- b) **A0**: Reflect about your research interests concerning your future MSc or PhD thesis and formulate a number of research topics. These topics should for BMI students fit at least one of the detailed learning objectives for biomedical informaticists described in the document 'BMI504-Spring2022-topic-requirements.pdf'. For students outside the BMI department, any topic will do. Be prepared to present and discuss this informally in class C2. No prior submission needed.

C2. Feb 9 / Ceusters /Fundamentals of science and research

Required reading pre-class:

Wagensberg, J., On the Existence and Uniqueness of the Scientific Method. Biol Theory, 2014. 9(3): p. 331-346. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4131153/pdf/13752 2014 Article 166.pdf [2]

Class structure:

- a) Traditional lecture on (1) philosophy of science and research and (2) the scientific method
- b) Students will report on pre-class assignment (b) and explain their ideas, each presentation followed by discussion.

Post-class assignment:

Required reading:

R3 Ioannidis, J.P., *Why most published research findings are false.* PLoS Med, 2005. **2**(8): p. e124. https://www.ncbi.nlm.nih.gov/pubmed/16060722 [3]

!!! This paper will be the topic of a closed book in-class test during class C3 !!!

C3. Feb 16 / Ceusters / Parameters for research designs

Pre-class reading:

R3 Ioannidis, J.P., *Why most published research findings are false*. PLoS Med, 2005. **2**(8): p. e124. https://www.ncbi.nlm.nih.gov/pubmed/16060722 [3]

Class structure:

- a) T1: Assessment of R3: in-class test (closed book) followed by discussion of correct answers.
- b) Lecture introducing various research designs

Post-class assignment:

- a) Optional reading:
 - **R4**. Abbasi, K., *Covid-19: politicisation, "corruption," and suppression of science.* BMJ, 2020. **371**: p. m4425. https://www.bmj.com/content/371/bmj.m4425 [4]
- b) Required readings:
 - R5 Ioannidis, J.P., Why Most Clinical Research Is Not Useful. PLoS Med, 2016. 13(6): p. e1002049. http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002049 [5]
 - R6 Ozonoff, D.M. and P. Grandjean, *What is useful research? The good, the bad, and the stable.* Environ Health, 2020. **19**(1): p. 2.[6] https://ehjournal.biomedcentral.com/articles/10.1186/s12940-019-0556-5
- c) On the basis of the lecture and papers **R4**, **R5** and **R6**, reflect further on concrete topics for your research proposal, and pick one for presentation during C4.

C4. Feb 23 / Ceusters / Planning of research projects

Pre-class readings:

- R4. Abbasi, K., *Covid-19: politicisation, "corruption," and suppression of science.* BMJ, 2020. **371**: p. m4425. https://www.bmj.com/content/371/bmj.m4425 [4]
- R5 Ioannidis, J.P., Why Most Clinical Research Is Not Useful. PLoS Med, 2016. 13(6): p. e1002049. http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002049 [5]
- R6 Ozonoff, D.M. and P. Grandjean, *What is useful research? The good, the bad, and the stable.* Environ Health, 2020. 19(1): p. 2.[6] https://ehjournal.biomedcentral.com/articles/10.1186/s12940-019-0556-5

Class structure:

Discussion of individual proposals. At the end of the class, the scope and goals of the projects should be clear.

Post-class assignment:

a) A1: Taking into account the content of all previous BMI504 lectures and papers, students must write an outline for their individual research project in the spirit of the scientific method thereby adapting the original ideas discussed in class in such a way that Ioannidis' features for assessing whether *clinical* research is useful come out positive for what they propose. This should be backed up by an initial literature study.

Due date: February 27 – noon

- b) Required reading:
 - R7 Delgado-Rodriguez, M. and J. Llorca, *Bias*. J Epidemiol Community Health, 2004. **58**(8): p. 635-41. https://jech.bmj.com/content/58/8/635 [7]

!!! This paper will be the topic of a closed book in-class test during class C5 !!!

C5. March 2 / Ceusters / Types of Bias

Pre-class reading:

R7 Delgado-Rodriguez, M. and J. Llorca, *Bias.* J Epidemiol Community Health, 2004. **58**(8): p. 635-41. https://jech.bmj.com/content/58/8/635 [7]

Class structure:

- a) Question answering re required reading
- b) T2: Assessment of R7: in-class test (closed book)
- c) Interactive lecture on various types of bias, followed by guided exercise.

Post-class assignment:

Suggested reading:

R8 Sudheesh, K., D.R. Duggappa, and S.S. Nethra, *How to write a research proposal?* Indian journal of anaesthesia, 2016. **60**(9): p. 631-634.

https://journals.lww.com/ijaweb/Fulltext/2016/60090/How to write a research proposal .4.aspx [8]

C6. Mar 9 / Ceusters / Qualitative research methods: theory and data collection methods

Pre-class reading:

R8 Sudheesh, K., D.R. Duggappa, and S.S. Nethra, *How to write a research proposal?* Indian journal of anaesthesia, 2016. **60**(9): p. 631-634.

https://journals.lww.com/ijaweb/Fulltext/2016/60090/How to write a research proposal .4.aspx [8]

Class structure:

Lecture on common qualitative data collection methods (Document Review, Observation, Interview (face-to-face), Focus Group Discussion, Ethnography, ...)

Post-class assignment:

Required reading:

R9 Palinkas, L.A., et al., *Mixed method designs in implementation research*. Adm Policy Ment Health, 2011. **38**(1): p. 44-53.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3025112/pdf/10488 2010 Article 314.pdf [9]

C7. Mar 16 / Ceusters / Mixed methods: Integration of quantitative and qualitative methods

Pre-class reading:

R9 Palinkas, L.A., et al., *Mixed method designs in implementation research*. Adm Policy Ment Health, 2011. **38**(1): p. 44-53.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3025112/pdf/10488 2010 Article 314.pdf [9]

Class structure:

- a) The first part will be an interactive lecture covering the topic.
- b) The second part will consist of a guided discussion aimed at determining the best research design to (dis)confirm hypotheses proposed for the individual research projects and to include an experimental design requiring a mixed design if not yet present in the original research proposal.

Post-class assignment:

a) A2: Students will update the first version of their research proposal (A1) so as to include all elements discussed in class and covered in the required readings thus far. Detailed instructions about format will be provided in class.

Due date: March 27 – noon

b) Required reading:

R10 Almoznino, G., et al., *The Dental, Oral, Medical Epidemiological (DOME) Study: Protocol and Study Methods.* Methods Inf Med, 2020. **59**(4-05): p. 119-130. [10] https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0040-1718582

C8. Mar 30/ Ceusters / Introduction to data analysis of quantitative and qualitative variables

Pre-class reading:

R10 Almoznino, G., et al., *The Dental, Oral, Medical Epidemiological (DOME) Study: Protocol and Study Methods.* Methods Inf Med, 2020. **59**(4-05): p. 119-130. [10]

Class structure: interactive lecture

Post-class assignment:

A3: Based on the slides and references used in lecture C8, students must rewrite their individual research project so that it satisfies all requirements with respect to (1) the precise research question, (2) the null-hypothesis, (3) the statistical null-hypothesis, (4) determination of all relevant variables (independent and dependent variables plus suggested methods for computing outcome variables) and (5) theoretical and operational linkage. Detailed instructions about format will be provided in class.

Due date: April 3 – noon

C9. Apr 6 / Ceusters / Elements of epidemiology

Class structure:

Lecture covering essential notions in population studies such as incidence, prevalence, mortality ratios, validity, reliability, sensitivity, and specificity, etc...

Post-class assignment:

a) **A4** Update, where needed, the proposal on the basis of C9-materials. This version will be used by the instructor of C11 to make that class maximally relevant to the students' research proposals.

Due date: April 10 – noon.

- c) Required reading:
 - R11 McCluskey, A. and A.G. Lalkhen, *Statistics II: Central tendency and spread of data*. Continuing Education in Anaesthesia Critical Care & Pain, 2007. **7**(4): p. 127-130. https://academic.oup.com/bjaed/article/7/4/127/466523 [11]
 - R12 Cohen, H.W., *P values: use and misuse in medical literature*. Am J Hypertens, 2011. **24**(1): p. 18-23.. [12] https://academic.oup.com/ajh/article/24/1/18/165807

!!! This paper will be the topic of a closed book in-class test during class C10 !!!

C10. Apr 13 / Ceusters / Descriptive and elementary statistics

Pre-class reading:

- McCluskey, A. and A.G. Lalkhen, *Statistics II: Central tendency and spread of data*. Continuing Education in Anaesthesia Critical Care & Pain, 2007. **7**(4): p. 127-130. https://academic.oup.com/bjaed/article/7/4/127/466523 [11]
- R12 Cohen, H.W., *P values: use and misuse in medical literature*. Am J Hypertens, 2011. **24**(1): p. 18-23.. [12] https://academic.oup.com/ajh/article/24/1/18/165807

Class structure:

- a) T3: closed book test on paper R12.
- b) Lecture covering the theories and applications of average value, median, mode, variance, standard deviation, inter-quartile range, skewness, kurtosis, histogram, box and whisker plot.

Post-class assignments:

Suggested reference book:

Norman, G. and D. Streiner, *Biostatistics : The Bare Essentials*. 2014, Shelton, UNITED STATES: People's Medical Publishing House. [13]
 Accessible through UB Libraries login: http://ebookcentral.proquest.com/lib/buffalo/detail.action?docID=3386956

C11. Apr 20/ Falls / Statistical analysis

Pre-class reading:

Suggested reference book:

Norman, G. and D. Streiner, *Biostatistics : The Bare Essentials*. 2014, Shelton, UNITED STATES: People's Medical Publishing House. [13]
 Accessible through UB Libraries login: http://ebookcentral.proquest.com/lib/buffalo/detail.action?docID=3386956

Class structure:

Lecture plus guided group work on statistics relevant to the students' research proposals. Completed assignments A4 will be used to determine the relevant content of the class. Possibilities are: 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:

A5: **Part 1:** For each student, questions will be designed addressing statistical problems relevant to the student's individual research project. Students will be expected to formally answer these questions with full, detailed explanations.

Part 2: Students will be given a mockup biomedical dataset and a set of questions related to the dataset. They must use the statistical skills and tests they were taught in the lecture to assess the characteristics of the dataset and select and carry out the appropriate statistical tests to answer the questions posed.

Due date: April 24 – noon

C12. Apr 27 / Ceusters / Clinical trial design

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, 2x2 factorial designs, cross over designs.

Post-lecture assignment:

- a) Required reading:
 - Mårtensson, P., et al., Evaluating research: A multidisciplinary approach to assessing research practice and quality. Research Policy, 2016. **45**(3): p. 593-603. https://www.sciencedirect.com/science/article/pii/S0048733315001845 [14]
- b) Students will complete their final research proposal (A6) and prepare a Powerpoint presentation (A7) of this proposal for formal presentation (A8) during C14.

Due date for A6: May 10 – noon Due date for A8: May 1 – noon

C13. May 4 / Ceusters / Presentation of final research proposals (first group of students)

Class structure: presentation of research proposals. Each student has 150 minutes divided by number of students participating, 75% of time for presentation, 25% for questions.

C14. May 11 / Ceusters / Presentation of final research proposals (second group of students)

Class structure: presentation of research proposals. Each student has 150 minutes divided by number of students participating, 75% of time for presentation, 25% for questions.

C15. FINAL EXAM: May 18 / 10AM

The final exam will be held online. It will be composed of questions and exercises covering the complete content of the course. Students may use any documentation they consider useful to consult during the exam, whether or not used during the course. They must do the exam however alone! Cameras need to be on all the time.

8 ATTENDANCE POLICY

Students are expected to attend *all* classes. For religious observances, university sanctioned events, athletic commitments and family/work obligations/emergencies, absences may be granted upon request and subsequent approval by the course director *prior* to the absence. Requests are to be sent by email. Medical absence must be accompanied by a doctor's note. Even if absence is granted, it 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 (http://www.buffalo.edu/administrative-services/emergency-management/emergency-procedures.html)

9 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 http://grad.buffalo.edu/Academics/Policies-Procedures/Academic-Integrity.html.
- 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.

10 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.

11 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 course director of this course. The office will provide you with information and review appropriate arrangements for reasonable accommodations. https://www.buffalo.edu/studentlife/who-we-are/departments/accessibility.html.

12 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.

13 AVAILABLE RESOURCES ON SEXUAL ASSAULT

UB is committed to providing an environment free of all forms of discrimination and sexual harassment, including sexual assault, domestic and dating violence and stalking. You may call <u>UB's Office of Equity, Diversity and Inclusion</u> at (716) 645-2266 for more information. https://www.buffalo.edu/equity.html

14 COUNSELING SERVICES:

As a student you may experience a range of issues that can cause barriers to learning or reduce your ability to participate in daily activities. These might include strained relationships, anxiety, high levels of stress, alcohol/drug problems, feeling down, health concerns, or unwanted sexual experiences. Counseling, Health Services, and Health Promotion are here to help with these or other concerns. You learn can more about these programs and services by contacting:

Counseling Services: 120 Richmond Quad (North Campus), phone 716-645-2720

202 Michael Hall (South Campus), phone: 716-829-5800

Health Services: Michael Hall (South Campus), phone: 716-829-3316 Health Promotion: 114 Student Union (North Campus), phone: 716-645-2837