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1. **Course Information**

- **Date(s)/Time(s):** Thursdays 10AM – 12.30/1PM
- **Location:** 5 Diefendorf, UB South campus
- **Delivery Mode:** Traditional
- **Number of Credits:** 3
- **Instructors**
  - Course director: Werner Ceusters, MD (contact: 77 Goodell street, 5th floor, on appointment: wceusters@gmail.com)
  - Lecturers:
    - Statistics: Sarah Mullin, MSc (contact: 77 Goodell street, 5th floor, on appointment: sarahmul@buffalo.edu)
    - All other topics: Werner Ceusters, MD (contact: 77 Goodell street, 5th floor, on appointment only through wceusters@gmail.com)

2. **Course Description**

- 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.
- Each class 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.
- 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)**

<table>
<thead>
<tr>
<th>Course Learning Outcomes; students will be able to:</th>
<th>BMI Graduate Program Outcomes / Competencies</th>
<th>Instructional methods</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Explain the fundamentals of scientific inquiry</td>
<td>O1: The most widely used clinical and informatics research methods</td>
<td>Lectures: C1, C2, C3, C4 Papers: R1, R2, R3, R4</td>
<td>Assignments: A1 Tests: T1 Final Exam</td>
</tr>
<tr>
<td>2. Articulate research questions</td>
<td>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</td>
<td>Lectures: C5, C6, C7 Papers: R6, R7</td>
<td>Assignments: A3, A5, A9, A11 Final Exam</td>
</tr>
<tr>
<td>3. Assess the quality of quantitative and qualitative studies</td>
<td>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</td>
<td>Lectures: C3, C4, C9 Papers: R4, R5, R9 Guided exercise in C3</td>
<td>Assignments: A2 Tests: T1, T2, T3 Final Exam</td>
</tr>
<tr>
<td>4. Understand and apply the concept of hypothesis in quantitative studies</td>
<td>O1: The most widely used clinical and informatics research methods. O5: Technical approaches to acquiring, modeling, representing and managing healthcare and biomedical research knowledge</td>
<td>Lectures: C5, C11 Papers: R6, R7</td>
<td>Assignments: A3, A6 Final Exam</td>
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<td>Course Requirements</td>
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<td>4. <strong>Course Requirements</strong></td>
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<td>• Students must attend all classes and must participate in class discussions. See attendance policy regulations on page 10 for exceptions,</td>
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<td>• Students are required to read 14 papers/book chapters/publications as listed in the course materials below.</td>
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<td>• 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 propose an alternative test or assignment for that class.</td>
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<td>• For several lectures, availability of laptop (hands-on, open-book tests) is required.</td>
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<td>• All assignments need to be completed prior to the deadline specified in the course schedule and send electronically to <a href="mailto:wceusters@gmail.com">wceusters@gmail.com</a> as a Microsoft Word document in attachment. Thus no Google doc links or any other link to a cloud server. 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”.</td>
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<td>• The first line in the document should always be your full name (first and last name).</td>
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<tr>
<td>• Assignments ordered by Mullin should in addition to be sent to <a href="mailto:wceusters@gmail.com">wceusters@gmail.com</a> be sent to <a href="mailto:sarahmul@buffalo.edu">sarahmul@buffalo.edu</a>.</td>
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<td>• 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.</td>
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<td>• When assignments A1, A2, A3, A5 or A7 are delivered past the due date, a penalty of 1% of the positive final score will be applied for every 24 hours of delay. When such assignment is not delivered at all, the penalty will be equal to the % for which</td>
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the assignment counts towards the final grade. Students unable to meet the deadline must inform the course director and instructor by email and provide a valid reason prior to reaching the deadline. An alternative assignment and/or due date can then be agreed upon, be it entirely to the discretion of the instructor.

- When assignments A4, A6 or A8 are not delivered in time, the student may choose to have the same regulations as for A1 etc. applied, or to carry the respective score weights over to assignment A9. In this case, the student will not receive feedback on the assignment which was overdue which may have a negative effect on the overall score of A9. Failure to deliver A9 prior to the due date will result in an F-grade for the course. Delivering a low-quality A9 will not necessarily lead to an F-grade for the course, but a low overall grade since this assignment contributes 35% to the overall final score. Failure to deliver A10 will result in a 0% for that assignment only, thus lowering the final score for 15%.

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.

<table>
<thead>
<tr>
<th>Class</th>
<th>Date</th>
<th>Instructor</th>
<th>Pre-class required readings</th>
<th>Assessments</th>
<th>Due dates</th>
<th>Final Score weight</th>
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</thead>
<tbody>
<tr>
<td>C1</td>
<td>30-Jan</td>
<td>Ceusters (1)</td>
<td>R1, R2</td>
<td>Post-class assignment A1</td>
<td>Feb 4 - noon</td>
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<tr>
<td>C2</td>
<td>06-Feb</td>
<td>Ceusters (2)</td>
<td>R3</td>
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<td>Ceusters (3)</td>
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<td>In-class closed book test T1</td>
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<td>Ceusters (4)</td>
<td>R5</td>
<td>In-class closed book test T2</td>
<td>Feb 25 - noon</td>
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<td>C5</td>
<td>27-Feb</td>
<td>Ceusters (5)</td>
<td>R6, R7</td>
<td>Post-class assignment A3</td>
<td>March 3 - noon</td>
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<td>C6</td>
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<td>Ceusters (6)</td>
<td>R8</td>
<td>Post-class assignment A4</td>
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<td>C7</td>
<td>12-Mar</td>
<td>Ceusters (7)</td>
<td>Post-class assignment A5</td>
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<td>C8</td>
<td>26-Mar</td>
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<td>C9</td>
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<td>R9</td>
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<td>09-Apr</td>
<td>Mullin (1)</td>
<td>R10, (R11)</td>
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<td>April 14 - noon</td>
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<td>C11</td>
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<td>Ceusters (10)</td>
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<td>23-Apr</td>
<td>Ceusters (11)</td>
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<td>C13</td>
<td>30-Apr</td>
<td>Ceusters (12)</td>
<td>R13</td>
<td>Post-class assignment A9</td>
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<td>C14</td>
<td>07-May</td>
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<td>R14</td>
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<td>Ceusters (14)</td>
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Scoring per student learning outcomes and assessments

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<tr>
<th>SLO</th>
<th>Tests</th>
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<th>A2</th>
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Final Grades:

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<tr>
<th>Grade</th>
<th>Quality Points</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A</td>
<td>4.0</td>
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<td>A-</td>
<td>3.67</td>
<td>90.0% - 92.9%</td>
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<tr>
<td>B+</td>
<td>3.33</td>
<td>87.0% - 89.9%</td>
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<tr>
<td>B</td>
<td>3.00</td>
<td>83.0% - 86.9%</td>
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<tr>
<td>B-</td>
<td>2.67</td>
<td>80.0% - 82.9%</td>
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<tr>
<td>C+</td>
<td>2.33</td>
<td>77.0% - 79.9%</td>
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<td>C-</td>
<td>2.00</td>
<td>73.0% - 76.9%</td>
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<td>C</td>
<td>1.67</td>
<td>70.0% - 72.9%</td>
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<tr>
<td>D+</td>
<td>1.33</td>
<td>67.0% - 69.9%</td>
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<td>D</td>
<td>1.00</td>
<td>60.0% - 66.9%</td>
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<td>F</td>
<td>0</td>
<td>59.9 or below</td>
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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. Error! Hyperlink reference not valid.

7. **Course Organization / Schedule**
Reference: [http://registrar.buffalo.edu/calendars/academic/](http://registrar.buffalo.edu/calendars/academic/)

C1. **Jan 30 / Ceusters / Course introduction – Introduction to research and research proposals/ SLO 1, 14**

**Pre-class assignments:**
- **a** required reading:
  - **All students:**
  - **PhD students, in addition to R1:**

  - **b** Reflect about your research interests concerning your future MSc or PhD thesis using R1 (and R2) as a guide, formulate a number of research topics within your research interests and describe where these topics fit in the findings reported on in R1. Be prepared to present and discuss this informally in class C1. No prior submission needed.

**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
- **d** Students will report on pre-class assignment (b) and explain their ideas, each presentation followed by discussion.
Post-class assignments:
   a) required reading:
      https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4131153/ [3]
   b) A1: Identify 5 claims or assertions within paper R3 that you consider to be important for appropriately doing research but which you had never heard of before or never seriously reflected upon. Explain/motivate for each claim/assertion very briefly – in one or two sentences – why you picked this one out. Use in your document appropriate citing and referencing of selected claims/assertions using Endnote (freely available for UB students - http://www.buffalo.edu/ubit/service-guides/software/by-title/endnote.html) or other citation system (Reference Manager, …) following the ‘Numbered’ reference style format as used in this syllabus.
      An example of a claim with appropriate citation and referencing would be:
      ‘It is quite possible for a reality to be perceived but for it to be difficult or impossible to observe.’ [3, p333].
      Motivation: I never realized the importance of the difference between perception and observation as defined in the paper.
      Due date: Feb 4 – noon.

C2. Feb 6 / Ceusters /Fundamentals of science and research / SLO 1

Required reading pre-class:

Class structure:
   Traditional lecture on (1) philosophy of science and research and (2) the scientific method

Post-class assignment:
   Required reading:
      https://jech.bmj.com/content/58/8/635 [4]
      !!! This paper will be the topic of a closed book in-class test during class C3 !!!

C3. Feb 13 / Ceusters / Types of Bias / SLO 1, 3

Class structure:
   a) Question answering re required reading
   b) T1: Assessment of R4: in-class test (closed book)
   c) Interactive lecture on various types of bias
   d) Guided exercise
   e) Discussion

Post-class assignment:
   Required reading:
      !!! This paper will be the topic of a closed book in-class test during class C4 !!!

C4. Feb 20 / Ceusters / Parameters for research designs / SLO 3

Class structure:
   b) Lecture introducing various research designs
   c) Organization of assignment

Post-class assignment:
   a) A2: Each student is assigned 3 research designs discussed in class. The task is to build a 4-column matrix with the 1st column containing all the design steps and features concerning at least 1 of the 3 designs, and the remaining columns, one for each research design, an annotation regarding (a1) whether, and if so, how, this step/feature figures in the design, (a2) the extent to which it is impacted by any of the 6 corollaries discussed in paper R5, and (a3) what should be done to minimize the effect.
Table Template:

<table>
<thead>
<tr>
<th>Steps and Features</th>
<th>[Design 1]</th>
<th>[Design 2]</th>
<th>[Design 3]</th>
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</tbody>
</table>

Due date: Feb 25 – noon

b) Required reading:
   
   [https://link.springer.com/content/pdf/10.1007%2Fs11135-017-0513-8.pdf](https://link.springer.com/content/pdf/10.1007%2Fs11135-017-0513-8.pdf) [7]

c) Prepare for discussion during class C5 topics for a course research project you are interested in.

C5. Feb 27 / Ceusters / Planning of research projects / SLO 2, 4, 14

Class structure:
   a) Lecture: Framework for team science research projects
   b) Discussion about possible research projects and final decisions

Post-class assignment:
   a) Required reading:
      [http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002049](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002049) [8]

   b) A3: After reading R8, and 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: March 3 – noon.

C6. March 5 / Ceusters / Qualitative research methods: theory and data collection methods / SLO 10, 11

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

Post-class assignment:
   a) A4: First draft of research proposal reflecting all aspects of the research endeavor discussed thus far in detail in all classes.

   Due date: Mar 10 – noon.
C7. Mar 12 / Ceusters / Elements of epidemiology / SLO 2, 6

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

Post-class assignment:
A5: Describe the inaccuracies that might arise in incidence and prevalence estimations on the basis of diagnostic codes retrieved from electronic healthcare records. Length doesn’t matter, correct identification of issues and argumentation does!

Due date: Mar 24 – noon.

Mar 19: NO CLASS: SPRING RECESS

C8. Mar 26 / Ceusters / Introduction to data analysis of quantitative and qualitative variables / SLO 4, 5, 11

Class structure: interactive lecture

Post-class assignment:

a) A6: 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.

Due date: March 31 – noon.

b) A summary of the proposal, containing only the points (1) to (4) under a) and of maximum 2 pages must be sent to both wceusters@gmail.com and sarahmul@buffalo.edu. This summary will be used by the instructor of C9 to make that class maximally relevant to the students research proposal.

Due date: April 2 – noon.

c) Required reading:

!!! This paper will be the topic of a closed book in-class test during class C9 !!!

C9. Apr 2 / Ceusters / Descriptive and elementary statistics / SLO 3, 6

Class structure:


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:

Required reading:

Suggested reference book:
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:
A7: For each student, a task will be designed addressing statistical problems relevant to the student’s individual research project. They will be given a mockup dataset that satisfies the descriptions of their research hypotheses and variables. They must determine the statistically relevant characteristics of the datasets and then select and carry out the appropriate statistical tests to (dis)prove the null-hypotheses of their proposal.

Due date: TO BE DETERMINED BY Sarah Mullin

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:
Required reading:

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-lecture assignment:
a) A8: Students will update their proposal with an experimental design by building further on the guided discussion.
Due date: April 28 – noon
b) Required reading:

Class structure: in-class exercise
a) during the first part, the class will use R13 and materials from all previous classes to develop an evaluation template for research proposals.
b) during the second part, students will evaluate using the template the research proposals of their peers.

Post-class assignment:
a) Required reading:
b) Students will complete their final research proposal (A9) and prepare a Powerpoint presentation (A10) of this proposal for formal presentation during C14.
Due date: May 5 – noon
C14. May 7 / Ceusters / Presentation of final research proposals / SLO 14

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 14 / 10AM
The final exam will be held in the classroom. 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.

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://emergency.buffalo.edu/campus-weather-alerts.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. http://www.student-affairs.buffalo.edu/ods/ Error! Hyperlink reference not valid.

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 UB’s Office of Equity, Diversity and Inclusion 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 can learn 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

15. **Course Materials**

- This course requires the following papers and electronic publications, all of which are available publicly or through the UB Libraries:


