Course Title: Introduction to Outcomes Research, Fall 2021
Course Number: EPID 0563
Course Pre- and Co-requisite(s): PHCO 0502 & PHCO 0504 (B and above)
Course Location: This course will meet remotely via Zoom:
https://rutgers.zoom.us/j/93487183885?pwd=UDhkdDR5UXFFL0tRSkZxcllCbXJpQT09
Meeting ID: 934 8718 3885
Password: 825289
Course Date & Time: Monday evenings (6-8pm)
Course Instructor: John Palatucci, MPA
Adjunct Faculty
Rutgers School of Public Health
Email: jpalatucci@sph.rutgers.edu
When emailing, please include [EPID 0563].
Office Hours: Wednesdays 10A-11A, or by appointment.
Office hours will be conducted via Zoom:
https://rutgers.zoom.us/j/93487183885?pwd=UDhkdDR5UXFFL0tRSkZxcllCbXJpQT09
Meeting ID: 934 8718 3885
Password: 825289
Course Assistant: TBD
Course Website: canvas.rutgers.edu
Required Course Text (PURCHASE):
Additional/Supplemental Readings/Resources (AVAILABLE VIA CANVAS):
Assigned chapters will be uploaded in Canvas.
Additional supplemental readings related to guest lecture presentations.
Course Description:
During the past few years, there has been an explosion of interest in measuring the outcomes of medical care. This has been called the outcomes movement. The science of measuring outcomes and of integrating that process into the routine care of patients has come to be known as outcomes research. Public health practitioners are expected to play a major role in evaluating the outcomes of medical care as the nation’s health care system is rapidly changing from fee-for-service to managed care environment. This course introduces students to the principles of health outcomes research and to practical applications of these principles.

Selected Concentration Competencies Addressed:
The following competencies are addressed in this course.

MPH degree in Epidemiology:
1. Formulate a specific hypothesis and determine an appropriate study design and analysis plan
2. Design, implement, and assess ordinary data collection systems for public health research
3. Communicate and present study findings to professional audiences

MS degree in HOPE:
4. Design, evaluate, interpret, and communicate the results of non-randomized, observational research for applications in health outcomes, health economics, and health policy research
5. Evaluate the reliability, validity, and generalizability of individual biomedical research studies
6. Synthesize evidence for health policy decision makers to facilitate translation of interventions, applications, or programs

Please visit the Concentration webpages on the School of Public Health’s website at sph.rutgers.edu for additional competencies addressed by this course for other degrees and concentrations.

Course Objectives:
By the completion of this course, students will be able to:

a. Discuss the concepts of clinical outcomes, economic outcomes, patient satisfaction and quality of life issues.
b. Identify sources of data for health outcomes research that are feasible to collect and minimize bias.
c. Evaluate alternative study designs for conducting health outcomes research.
d. Discuss the utility of emerging research methods in outcomes research.
e. Discuss the concepts of quality of health care organizations and value-based care.
f. Demonstrate an understanding of the process of manuscript development and evidence communication.
g. Evaluate the efficacy of newly introduced medical technologies through meta-analytic techniques.

h. Apply decision analysis techniques to evaluate the usefulness of alternative clinical and public health interventions.

i. Design and conduct a study using health outcomes research methodology to inform decision-making

**Course Requirements and Grading:**

1. Reflections on Guest Speakers .......................... 15 pts.
2. Midterm (online) ........................................... 30 pts.
3. Final Project – “Research Grant Proposal”
   b. Draft Approach section ................................. 5 pts.
   c. Presentation (via “My Media”/Canvas) ............... 15 pts.
   d. Final Proposal (Aims, Significance, Innovation and Approach) 20 pts.
4. Class Participation (Online30 & Attendance) ........ 10 pts.
   **Total:** .................................................. 100 pts.

- **Late Assignments:** All assignments, unless otherwise indicated, must be submitted via Canvas by 11:59 PM on due date. 5% of assignment score will be deducted for each day late following the submission.

- **Reflections on Guest Speakers (15% of Grade):** Students will write three (3) reflections over the course of the semester. The response should include a summary of the talk, how the presentation is relevant to the student’s research interests or career aspirations, and what was learned. (300-500 words each).

- **Mid-term exam (30% of Grade):** Students will be given an exam in week 9. The test will consist of multiple-choice, fill-in and short answer. (~45 questions, 120 minutes-max)

- **Research Proposal (45% of Grade):** Students will prepare select components for a National Institute of Health-style grant proposal: abstract (1 paragraph, 0.5 page/single-spaced/11pt font), specific aims page (1 page/single-spaced/11pt font), and research plan (significance, innovation, and approach sections, no more than 6 pages/single-spaced/11pt font). A draft of the aims page is due week 6. A draft of the approach is due week 11. The complete proposal is due at the end of semester. There is a presentation and a final draft due in the final two weeks of the semester.

- **Class Participation (10% of Grade):**
  1) **Be Respectful.** This includes interaction with guest speakers and classmates, timeliness, and communication.
  2) **Be Present** (Physically and Mentally). Attendance is mandatory (see school policy on remote courses, below). Absences may be excused on a case-by-case basis. You must notify the instructor before class begins. Participation in Online 30 is mandatory.
  3) **Online 30** – Throughout the semester, we will use Canvas to host online discussions on course readings, the final project, and speakers. This is incorporated into the “Class Participation” grade and is expected to take an additional 30 minutes per week.
• **Make-Up Work Policy**
  In cases of short-term illness or personal crises, the Instructor may grant permission to make up missed tests or assignments and/or request that the student complete a unique make-up assignment for partial credit. This will be determined on a case-by-case basis upon consultation with the Instructor and requires formal documentation (for example, a doctor’s note). Prolonged absences will be addressed on a case-by-case basis in consultation with the Associate Dean for Student Affairs.

Alignment of Competency:

<table>
<thead>
<tr>
<th>Competency</th>
<th>Course Objectives(s)</th>
<th>Lessons</th>
<th>Assessment(s)</th>
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</table>
| 1          | a. Discuss the concepts of clinical outcomes, economic outcomes, patient satisfaction, and quality of life issues.  
  b. Identify sources of data for health outcomes research that are feasible to collect and minimize bias.  
  c. Evaluate alternative study designs for conducting health outcomes research.  
  d. Discuss the utility of emerging research methods in outcomes research.  
  f. Demonstrate an understanding of the process of manuscript development and evidence communication.  
  i. Design and conduct a study using health outcomes research methodology to inform decision-making                                                                                     | Weeks 1-8 | 1, 2, 3.a, 3.b, 3.c, 3.d |
| 2          | a. Discuss the concepts of clinical outcomes, economic outcomes, patient satisfaction, and quality of life issues.  
  b. Identify sources of data for health outcomes research that are feasible to collect and minimize bias.  
  c. Discuss the utility of emerging research methods in outcomes research.                                                                                                                                       | Weeks 1-8 | 1, 2, 3.a, 3.b, 3.c, 3.d |
| 3          | c. Evaluate alternative study designs for conducting health outcomes research.  
  g. Evaluate the efficacy of newly introduced medical technologies through meta-analytic techniques.                                                                                                             | Weeks 1-8, 10-12 | 1, 3.c, 3.d |
| 4          | g. Evaluate the efficacy of newly introduced medical technologies through meta-analytic techniques.  
  h. Apply decision analysis techniques to evaluate the usefulness of alternative clinical and public health interventions.                                                                                   | Weeks 10-13 | 1, 3.a, 3.b, 3.c, 3.d |
| 5          | e. Discuss the concepts of quality of health care organizations and value-based care.  
  g. Evaluate the efficacy of newly introduced medical technologies through meta-analytic techniques.                                                                                                          | Weeks 10-13 | 1, 2, 3.c, 3.d, 4 |
h. Apply decision analysis techniques to evaluate the usefulness of alternative clinical and public health interventions.
i. Design and conduct a study using health outcomes research methodology to inform decision-making

| 6 | i. Design and conduct a study using health outcomes research methodology to inform decision-making | Weeks 1-13 | 1, 2, 3.a, 3.b, 3.c, 3.d |

Grading Policy:

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<tr>
<th>Score Range</th>
<th>Grade</th>
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<tr>
<td>94 – 100</td>
<td>A</td>
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<tr>
<td>90 – &lt;94</td>
<td>A-</td>
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<td>87 – &lt;90</td>
<td>B+</td>
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<td>84 – &lt;87</td>
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<td>77 – &lt;80</td>
<td>C+</td>
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<tr>
<td>70 – &lt;77</td>
<td>C</td>
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<td>&lt;70</td>
<td>F</td>
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Course Schedule:

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<tr>
<th>Week</th>
<th>Course Topic and Assigned Reading</th>
<th>Assignments and Online 30</th>
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<tbody>
<tr>
<td>Week 1 9/13</td>
<td><strong>Introduction to Outcomes Research</strong>&lt;br&gt;Midterm prep: • Read Syllabus &amp; Kane (2011, Chap. 1)&lt;br&gt;Final project: • Read “How to develop a novel and compelling idea.” • Explore interests through searching Google, GoogleScholar, PubMed, and Rutgers Library.</td>
<td>Obtain course text (Due 9/13) Online 30 (Due 9/17): • Introduce yourselves via discussion board &amp; review requirements for final project.</td>
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<td>Week 2 9/20</td>
<td><strong>Causal Thinking &amp; Study Design</strong>&lt;br&gt;Midterm prep: • Kane (2011, Chap. 2 &amp; 3)&lt;br&gt;Final project: • Read “Specific aims section: conceptual framework for creating a bulleted outline.” • Continue to explore interests through searching Google, GoogleScholar, PubMed, and Rutgers Library.</td>
<td>Online 30 (Due 9/24): • Review and respond to classmate introductions (minimum of 3 reviews). • Post a scholarly/peer-review article related to outcomes research that interests you.</td>
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<td>Week 3 9/27</td>
<td><strong>Scientific Measurement</strong>&lt;br&gt;Midterm prep: • Kane (2011, Chap.4)&lt;br&gt;Final project: • Read “Writing the specific aims section.”</td>
<td>Online 30 (Due 10/1): • Review/respond to classmate posts on scholarly/peer-review articles.</td>
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<td>Week</td>
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<td>• Review examples of specific aims sections available via Canvas.</td>
<td>• Post your initial ideas/brainstorm for the final project.</td>
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| **Week 4** 10/4 | **Generic Outcomes Measures**  
Midterm prep:  
• Kane (2011, Chap.5)  
Final project:  
• Use “Specific aims section… a bulleted outline” to outline your aims page. | **Online 30 (Due 10/8):**  
• Read/respond to classmates’ initial ideas/brainstorm for the final project.  
• Ask questions or explain material we have covered. |
| **Week 5** 10/11 | **Humanistic Outcomes Measures (Quality of Life & Patient Satisfaction)**  
Midterm prep:  
• Develop study guide  
Speaker Reflections:  
• Pizzi readings available via Canvas.  
Final project:  
• Collect references for your aims page. | **Online 30 (Due 10/15):**  
• Read/respond to explanations/questions from classmates on the material covered  
• Post initial questions for Dr. Pizzi (next week’s lecture) |
| **Week 6** 10/18 | **Health Economics Outcomes**  
Laura T. Pizzi, PharmD, MPH  
Professor and Director, Center for Health Outcomes, Policy, and Economics (HOPE), Ernest Mario School of Pharmacy  
Midterm prep:  
• Develop study guide  
Speaker Reflections:  
• Dhanda readings available via Canvas  
Final project:  
• Read “Research strategy section: significance and innovation”  
• Review examples of significance and innovation sections provided via Canvas | **First Draft Aims Page (Due 10/18)**  
**Online 30 (Due 10/22):**  
• Review and Respond to Classmate Posts on questions for Dr. Pizzi  
• Post initial questions for Dr. Dhanda (next week’s lecture) |
| **Week 7** 10/25 | **Clinical Outcomes**  
Devender Dhanda, PhD, MBA, MS  
Associate Director, Economic & Predictive Modelling Lead, WWHEOR, Bristol-Myers Squibb  
Midterm prep:  
• Complete/review study guide  
Speaker Reflections:  
• Mearns readings available via Canvas  
Final project:  
• Read “Research strategy section: approach subsection”  
• Review Examples of approach sections provided via Canvas | **Online 30 (Due 10/29):**  
• Review/respond to classmate posts on questions Dr. Dhanda  
• Post initial questions for Dr. Mearns (next week’s lecture) |
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<td>Week 8 11/1</td>
<td><strong>Systematic Review and Meta-Analysis</strong> &lt;br&gt;Elizabeth Mearns, PharmD &lt;br&gt;Senior Manager, US HEOR, Hematology/Oncology, Celgene <strong>Midterm prep:</strong> &lt;br&gt;• Complete/review study guide</td>
<td><strong>Guest Speaker Reflection I</strong> &lt;br&gt;(Due 11/1) &lt;br&gt;<strong>Online 30 (Due 11/5):</strong> &lt;br&gt;• Review/respond to classmate posts on questions for Dr. Mearns</td>
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<td>Week 9 11/8</td>
<td><strong>MIDTERM EXAM (Delivered through Canvas)</strong> &lt;br&gt;• <strong>Content:</strong> Kane, Chapters 1-5. &lt;br&gt;<strong>Final Project:</strong> &lt;br&gt;• Outline significance and innovation sections &lt;br&gt;<strong>Speaker Reflections:</strong> &lt;br&gt;• Iyer readings available via Canvas</td>
<td><strong>MIDTERM EXAM</strong> &lt;br&gt;Available only on 11/8, within 2pm-10pm ET window &lt;br&gt;• Delivered through Canvas &lt;br&gt;<strong>Online 30 (Due 11/12):</strong> &lt;br&gt;• Post initial questions for Dr. Iyer (next week’s lecture)</td>
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<td>Week 10 11/15</td>
<td><strong>Emerging Outcome Research Design and Methods</strong> &lt;br&gt;Neeraj Iyer, Phd, Bpharm &lt;br&gt;Director, Value Evidence &amp; Outcomes, Novo Nordisk &lt;br&gt;<strong>Speaker Reflections:</strong> &lt;br&gt;• Tak Piech readings available via Canvas &lt;br&gt;<strong>Final Project:</strong> &lt;br&gt;• Work on approach section</td>
<td><strong>Online 30 (Due 11/19):</strong> &lt;br&gt;• Review/respond to classmate posts on questions for Dr. Iyer &lt;br&gt;• Post initial questions for Ms. Tak Piech (next week’s lecture)</td>
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<td>Week 11 11/22</td>
<td><strong>Global Acceptance of Outcomes Research in Market Access Decisions and Policymaking</strong> &lt;br&gt;Catherine Tak Piech, MBA &lt;br&gt;VP, Value Assessment Strategy (ret.) &lt;br&gt;The Janssen Pharmaceutical Companies of Johnson &amp; Johnson &lt;br&gt;<strong>Speaker Reflections:</strong> &lt;br&gt;• TBD readings available via Canvas</td>
<td><strong>First Draft Approach Section (Due 11/22)</strong> &lt;br&gt;<strong>Online 30 (Due 11/26):</strong> &lt;br&gt;• Review/respond to classmate posts on questions for Ms. Tak Piech &lt;br&gt;• Post initial questions for Ms. TBD (next week’s lecture)</td>
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<td>Week 12 11/29</td>
<td><strong>Real World Evidence to Support Regulatory Decision Making</strong> &lt;br&gt;TBD &lt;br&gt;<strong>Speaker Reflections:</strong> &lt;br&gt;• Beamesderfer readings available via Canvas</td>
<td><strong>Guest Speaker Reflection II</strong> &lt;br&gt;(Due 11/29) &lt;br&gt;<strong>Online 30 (Due 12/3):</strong> &lt;br&gt;• Review/respond to classmate posts on questions for Ms. TBD &lt;br&gt;• Post initial questions for Ms. Beamesderfer (next week’s lecture)</td>
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| Week 13 12/6 | **Outcomes Research Manuscript Development & Publishing**  
            Lyn Beamesderfer, MS  
            Associate Director, Publications & Communications, ISPOR  
            **Final Project:**  
            • Complete proposal and presentations | **Online 30 (12/10):**  
            • Review/respond to classmate posts on questions for |
| Week 14 12/13 | **Course Wrap-up I**                                                   | **Upload Student Presentations to Canvas** |
| Week 15 12/20 | **Course Wrap-up II**                                                  | **Guest Speaker Reflection III (Due 12/13)** |
|          | Review and Comment on Student Presentations                           | **Due: Final Draft of Research Proposal Components (Due 12/20)** |

**School of Public Health Policies (Fall 2021):**

**Special Circumstances During COVID-19:** The School of Public Health recognizes that students may experience challenges or be negatively impacted due to the COVID-19 pandemic, mental and emotional health toll from systemic racism, altered personal and professional obligations, and other crises existing at the moment in our local, national, and global communities. Students are encouraged to discuss these challenges and circumstances with their instructor, if they feel they may need additional support or temporary accommodations at the beginning or during this course. The course instructor may consider making reasonable temporary adjustments depending on the student’s situation. If additional support is needed, students may reach out to the Office of Student Affairs (studentaffairs@sph.rutgers.edu) or any of the appropriate referral resources listed on the Student Connect Canvas page.

**Syllabus Addendum: Remote Learning Policies – FOR REMOTE COURSES:** As you know, we are engaged in this course under extraordinary circumstances. Not only are we now conducting the class remotely, but we are all working under the repercussions of the COVID-19 pandemic. The following are class policies for our class sessions with Zoom. Please read carefully; these policies apply to the Fall 2021 semester. All students are expected to adhere to the policies.

**General:** Log into Zoom using your Rutgers NetID and sign-in with your full first name and last name as listed on the class roster. (If you use a different name than what is listed on the class roster, please email the instructor in advance of the class or send a private Chat message.) Using your full name allows the instructor to know who is in attendance and to quickly sort students into their groups when needed. Users who do not log into Zoom using their Rutgers NetID may have trouble accessing the Zoom classroom.

**Video:** Please turn on your video when possible. We recognize that this isn’t always easy but this will help to build our class community. Seeing the faces of your classmates more closely duplicates the typical i-
person learning experience and may shift your mindset into more focus and attention. Seeing each other can also provide each of us with positive social interactions.

- If you're unable to find an environment without a lot of visual distractions or prefer to not show your living space as a background, feel free to use a virtual background (several virtual background images created by the School of Public Health are available in the Student Connect Canvas page).
- To save bandwidth, there may be times during class when the instructor asks students to turn off videos.
- Add a photo to your Zoom profile. (Then in times when videos are off, we'll see photos of everyone rather than an empty box.)
- If you have limited internet bandwidth or other issues impacting your video use, please inform the instructor.

Audio: Mute your microphone when you are not talking. This helps eliminate background noise.

- Use a headset, if possible. If you own headphones with a microphone, please use them. This improves audio quality.
- Be in a quiet place, if possible. Turn off any music, videos, etc. in the background.

Chat: Stay on topic and be respectful. Use the chat window for questions and comments that are relevant to class.

NOTE: Class meetings on Zoom will be recorded and made available for students in the course on Canvas only

Learning Management System: Canvas will be used extensively throughout the semester for course syllabus, assignments, announcements, communication and/or other course-related activities. It is the student’s responsibility to familiarize themselves with Canvas and check it regularly. If you have difficulties accessing Canvas, please inform the instructor and Canvas Support (help@canvas.rutgers.edu). Canvas is accessible at canvas.rutgers.edu.

School of Public Health Honor Code: The School of Public Health Honor Code is found in the School Catalog (sph.rutgers.edu/academics/catalog.html). Each student bears a fundamental responsibility for maintaining academic integrity and intellectual honesty in his or her graduate work. For example, all students are expected to observe the generally accepted principles of scholarly work, to submit their own rather than another’s work, to refrain from falsifying data, and to refrain from receiving and/or giving aid on examinations or other assigned work requiring independent effort. In submitting written material, the writer takes full responsibility for the work as a whole and implies that, except as properly noted by use of quotation marks, footnotes, etc., both the ideas and the works used are his or her own. In addition to maintaining personal academic integrity, each student is expected to contribute to the academic integrity of the School community by not facilitating inappropriate use of her/his own work by others and by reporting acts of academic dishonesty by others to an appropriate school authority. It should be clearly understood that plagiarism, cheating, or other forms of academic dishonesty will not be tolerated and can lead to sanctions up to and including separation from the Rutgers School of Public Health.

Students with Disabilities: Rutgers University welcomes students with disabilities into all of the University’s educational programs. In order to receive consideration for reasonable accommodations, a student must apply for Services by first completing a Registration Form with the Rutgers Office of Disability Services (ODS) at ods.rutgers.edu. The student will also be required to participate in an ODS intake interview and provide documentation. If reasonable accommodations are granted, ODS will provide you with a Letter of Accommodations which should be shared with your instructors as early in your courses as possible.

Commitment to Safe Learning Environment: The Rutgers School of Public Health is committed to helping create a safe learning environment for all students and for the School as a whole. Free expression in an academic community is essential to the mission of providing the highest caliber of education possible. The School encourages civil discourse, reasoned thought, sustained discussion, and constructive engagement. Provocative ideas respectfully presented are an expected result. An
enlightened academic community, however, connects freedom with responsibility. The School encourages all students to disclose any situations where you may feel unsafe, discriminated against, or harassed. Harassment or discrimination of any kind will be not tolerated and violations may lead to disciplinary actions.

**Reporting Discrimination or Harassment:** If you experience any form of gender or sex-based discrimination or harassment, including sexual assault, sexual harassment, relationship violence, or stalking, know that help and support are available. You may report such incidents to the RBHS Title IX Office or to the School of Public Health's Office of Student Affairs. Rutgers University has staff members trained to support survivors in navigating campus life, accessing health and counseling services, providing academic and housing accommodations, and more. If you experience any other form of discrimination or harassment, including racial, ethnic, religious, political, or academic, please report any such incidents to the School’s Office of Student Affairs. The School strongly encourages all students to report any incidents of discrimination or harassment to the School. Please be aware that all Rutgers employees (other than those designated as confidential resources such as advocates, counselors, clergy and healthcare providers as listed in Appendix A to Policy 10.3.12) are required to report information about such discrimination and harassment to the School and potentially the University. For example, if you tell a faculty or staff member about a situation of sexual harassment or sexual violence, or other related misconduct, the faculty or staff member must share that information with the RBHS Title IX Coordinator. If you wish to speak to a confidential employee who does not have this reporting responsibility, you can find a list of resources in Appendix A to University Policy 10.3.12. For more information about your options at Rutgers, please visit Rutgers Violence Prevention and Victim Assistance.

**Graduate Student Computer Policy:** Students are required to possess a personal laptop, no older than approximately two years, that must meet minimum requirements which may be found online at: [sph.rutgers.edu/student-life/computer-support.html](http://sph.rutgers.edu/student-life/computer-support.html)

**Policy Concerning Use of Recording Devices and Other Electronic Communications Systems:** When personally owned communication/recording devices are used by students to record lectures and/or classroom lessons, such use must be authorized by the faculty member or instructor who must give either oral or written permission prior to the start of the semester and identify restrictions, if any, on the use of mobile communications or recording devices.

**Policy Concerning Use of Turnitin:** Students agree that by taking this course all required papers may be subject to submission for textual similarity review to Turnitin.com (directly or via learning management system, i.e. Canvas) for the detection of plagiarism. All submitted papers will be included as source documents in the Turnitin.com reference database solely for the purpose of detecting plagiarism of such papers. Use of the Turnitin.com service is subject to the Usage Policy posted on the Turnitin.com site. Students who do not agree should contact the course instructor immediately.

**Withdrawal/Refund Schedule:** Students who stop attending their course(s) without submitting a completed Add/Drop Course form will receive a failing grade. Furthermore, students dropping to zero credits for the semester are considered withdrawn and must submit a completed Leave of Absence form from the School of Public Health’s Office of Student Affairs. The School of Public Health refunds tuition only. Administrative and technology fees are non-refundable. You may find the Withdrawal/Refund Schedule on the School of Public Health website at: [sph.rutgers.edu/academics/academic-calendar.html](http://sph.rutgers.edu/academics/academic-calendar.html)