PHCY 5144 Patient Reported Outcomes  
2 Credit Hours

Background
Patient-reported outcomes (PROs) refer to various methods used to capture the patient perspective, and may include symptoms, functioning, health-related quality of life (HRQOL), or patient-perceived health status. These measures provide important information that is increasingly being used to inform health care decision-making.

Course Description
This course is designed to provide an overview of methods pertaining to the development and evaluation of PROs and the role they play in regulatory, reimbursement, and market access decisions.

Course Purpose
The purpose of this course is to provide an understanding of both the design and application of PROs with respect to drug approval and health technology assessment.

Place and Time of Class Sessions
This course will be taught primarily in a synchronous fashion. Virtual classroom sessions will be held live each week on Sunday afternoon from 3:00pm to 5:00pm Wyoming time. Students will be responsible for completing course materials as their time permits, each week, during the 5 weeks of the course, with quizzes and exams being administered on weekends. Discussion board sessions will be held around the clock during the course. Students are expected to actively participate in discussion board on a regular basis. Questions regarding course content should be posted to the discussion board to allow access by all students to the discussion of this course material.

Course Faculty and Office Hours
Course Coordinator:
Kristin Khalaf Gillard, PharmD, PhD
Email: kkhalaf@uwyo.edu
Office Hours: by appointment

Course Objectives
Upon successful completion of this course, the student will be able to:
1. Understand how PROs fit into the context of clinical outcome assessments (COAs) from a regulatory perspective
2. List and define the different types of PROs, and select the most appropriate PRO to use for different research objectives
3. Describe the standard process by which PRO measures are developed and evaluated, and critically evaluate the measurement properties of a PRO
4. Understand the concept of utility, methods to elicit patient preferences, and the role of preference indices in health technology assessment
5. Describe the steps involved in cross-culturally adapting existing PRO measures
6. Interpret and critically analyze published outcomes research
**Course Learning Resources:**

- **Required textbook:**
- **Additional assigned reading material** (reading and/or video) will be provided on a weekly basis.
- **Additional recommended textbook** (not required; will post individual chapters online as per reading list):

**Course Structure & Outline**

Live online virtual classes will be held each week for 5 weeks using the virtual classroom (via Zoom). Class will be held on April 15 (week 1), April 22 (week 2), April 29 (week 3), May 6 (week 4), and May 13 (week 5). Class attendance is mandatory. Homework will be assigned following weeks 1, 2, and 4. A midterm examination will be administered following week 3. The final exam will be due on May 15 by midnight.

**Evaluation Techniques:**

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Points</th>
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<tbody>
<tr>
<td>Class participation (including discussion boards)</td>
<td>50</td>
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<tr>
<td>Homework Assignment 1</td>
<td>10</td>
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<tr>
<td>Homework Assignment 2</td>
<td>10</td>
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<tr>
<td>Homework Assignment 3</td>
<td>10</td>
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<tr>
<td>Midterm Exam</td>
<td>30</td>
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<tr>
<td>Final Exam</td>
<td>50</td>
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**Total Points** 160 points

**Grading:**

- **A:** 90.0 – 100.0
- **B:** 80.0 – 89.9
- **C:** 70.0 – 79.9
- **D:** 60.0 – 69.9
- **F:** <60.0

**Class Attendance Policy**

Students must attend all five (5) classes, and productively participate in discussion board. Each student is expected to initiate one original thread per week and one responsive thread that follows the original thread posted by another student. All threads, whether original or responsive, must relate directly to the course material for that week, and must indicate reflective consideration of the material.

**Quiz/Exam Policy**

Inquiries regarding exams should be directed to the course coordinator, preferably prior to the assessment, and always within a week following the assessment.
Re-Grading Policy
Requests for a re-grade of an examination, quiz, assignment, or in-class preparedness/participation points, must be requested within 2 business days of the return of the examination, quiz, or assignment. If the 2 business day period elapses and the student does not realize this, the request for a re-grade will NOT be considered. All requests for re-grading must be made in a written statement to the course coordinator and must be supported by appropriate justification (required textbooks, reading assignments, lecture citations). A request for re-grading is a re-evaluation of your work and has the potential to increase or decrease your grade when your work is reconsidered.

Make-up Quiz/Exam Policy
Students who are not excused from a missed quiz or exam will receive a grade of zero on that missed assessment. Any student who misses quizzes and/or exams of a sufficient number that indicate the student has not completed enough coursework to achieve the objectives of the course will be given an incomplete (I) grade for the course.

Policy on Old Quizzes and Assignments
Be advised that exams are an official University document, and not a public record, and therefore may not be communicated, copied or reproduced by any means, either in whole or in part, or shared with others in any form. Violators will be subject to discipline.

Academic Dishonesty Statement:
The University of Wyoming is built upon a strong foundation of integrity, respect and trust. All members of the university community have a responsibility to be honest and the right to expect honesty from others. Any form of academic dishonesty is unacceptable to our community and will not be tolerated. Teachers and students should report suspected violations of standards of academic honesty to the instructor, department head, or dean. Other University regulations can be found at: http://uwadmnweb.uwyo.edu/legal/universityregulations.htm

Disability Support Statement:
The University of Wyoming is an affirmative action/equal opportunity educator and employer. If you have a physical, learning, or psychological disability and require accommodations, please let the instructor know as soon as possible. You will need to register with, and provide documentation of your disability to University Disability Support Services (UDSS) in SEO, room 330 Knight Hall. The University Disability Support Services website, which may be found at: http://uwadmnweb.uwyo.edu/udss/facultyandstaff/tipsforteaching.asp or you may contact UDSS for more information at (307) 766-6189, TTY: (307) 766-3073.
Course Schedule, Required Readings, and Assignments

Class will begin on April 15 and end on May 13. The final examination will be due by midnight on May 15 (final grades are due by noon on May 17).

<table>
<thead>
<tr>
<th>Week (Date)</th>
<th>Topic and Readings</th>
<th>Assignment</th>
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<tbody>
<tr>
<td>1 (April 15)</td>
<td>Topics:</td>
<td></td>
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<tr>
<td></td>
<td>• Course Introduction</td>
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<td></td>
<td>• Overview of Clinical Outcomes Assessments</td>
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<td></td>
<td>• Patient-reported Outcomes: Basic Concepts</td>
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<td>Required Readings:</td>
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<tr>
<td></td>
<td>– Streiner &amp; Norman Chapter 1-2</td>
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<td></td>
<td>Supplemental:</td>
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<td>2 (April 22)</td>
<td>Topics:</td>
<td>Homework 2 Assigned (Due April 28)</td>
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<tr>
<td></td>
<td>• Validity</td>
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<td></td>
<td>• Qualitative Research Methods for Developing PROs</td>
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</table>
**Readings:**
- Streiner & Norman. Chapters 3, 4, 5, & 6

**Supplemental:**
- Streiner & Norman Chapter 10, Chapter 5 pp. 79-80 (Face Validity)

| **Topics:**  
- Introduction to measurement  
- Quantitative Evaluation of PROs  

| **Readings:**  
- Streiner & Norman Chapter 8, Chapter 12 “Introduction to Item Response Theory” and “Problems with Classical Test Theory” (p. 273-275)  
### Supplemental:
- Streiner & Norman Chapter 9
- Streiner & Norman Chapter 12

### Topics:
- Measurement wrap-up
- Regulatory considerations for the use of PROs in clinical development

### Readings:
- United States Department of Health and Human Services Food and Drug Administration. Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. 2009. (pp. 1-20, up to Section F)

### 4 (May 6)

**Homework 3 Assigned**

(Due May 12)

### Topics:
- **Electronic PROs, Special Populations (e.g., children, oncology), Translation and Cultural Adaptation; FDA Drug Development Tool Qualification Program, EMEA PRO Guidance**
- **Utilities: Preference Elicitation Methods and Applications**
- **Wrap-up**

### Readings:

**5 (May 13)**

Final Exam Due May 15 (midnight)

**Supplemental:**