CLRES 2040 Measurement in Clinical Research

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<tr>
<th>Course Information</th>
<th>Class Meetings</th>
<th>Instructor(s)</th>
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<td>Term: Summer</td>
<td>TBD</td>
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<td>Credits: 1</td>
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Course Description
This course explores measurement issues in clinical research and provides concrete examples of such issues. The course will focus primarily on providing students with practical skills that will allow them to locate, select, and evaluate instruments for use in clinical research. Key aspects of measure reliability (e.g., inter- and intra-rater, test-retest, internal consistency) and validity (e.g., content, criterion, construct) will be examined in detail. Additional topics include sociodemographic issues in measurement, survey research methods, and factor analysis. By the end of the course, you should be able to:

- Recognize the universality and complexity of measurement issues
- Discuss measurement issues in students’ specific areas of research interest
- Become familiar with methods for examining the measurement properties of instruments
- Discuss reliability and validity evidence for specific instruments
- Generate a comprehensive team-based review of a measurement issue

Course Format
This course will be in a hybrid – or flipped – format. Rather than coming to class for lectures, you’ll watch video lectures on your own time, then come to class to discuss and apply what you’ve learned. The hybrid format allows you to:

- Engage with the content at your own pace and on your own schedule
- Rewind, rewatch, or jump ahead as necessary
- Use class time for interaction and clarification
- Spend less total time in class

The hybrid format also requires you to take more responsibility for your own learning, so please be proactive about seeking help if you have questions or are confused.

Prerequisites
- Basic familiarity with research methods
- Basic computer skills
Required Materials
Articles: To access assigned journal articles, please visit: http://www.ncbi.nlm.nih.gov/pubmed?cmd=search

Weekly Responsibilities
Each week, you will complete the designated online course materials (lecture videos, readings, and assignments) before coming to class. Be sure to take notes on videos and readings, write down any questions you have, and bring them with you to class. These materials are required, not optional. I expect you to come to class fully prepared to discuss and apply what you’ve learned. I also expect you to ask for clarification and help when you need it.

Course Requirements
In addition to completing weekly modules and attending class sessions, you will complete seven team assignments and take a cumulative final exam. You will find the task descriptions and deadlines for assignments in the Assignments section of CourseWeb.

Grading
Your course grade will be based on your performance on your team assignments and final exam.
- Team assignments: 50%
- Final exam: 50%

Final letter grades will be assigned according to the following grading scale:
A+ = 98-100; A = 93-97; A- = 90-92; B+ = 88-89; B = 83-87; B- = 80-82; C+ = 78-79; C = 73-77; C- = 70-72;
D+ = 68-69; D = 63-67; D- = 60-62; F = 0-59

Help
Please don’t hesitate to contact me via email if you have any questions about course content. You can generally expect an answer within 24 hours, if not sooner.

If you have any questions about scheduling or technology (CourseWeb, GoToMeeting, the sign-in system for attendance, etc.) please contact the course administrator, Juliana Tambellini at: tambellinijm2@upmc.edu.

Course Policies
You are responsible for knowing and following these course policies. Please read them carefully.

Attendance Policy
Please sign in to each class on the computer provided in suite lobby; this records your attendance. If you encounter a problem with the sign-in system, please contact the course instructor(s) immediately.

Recording Policy
ICRE Produced Recordings: ICRE faculty and/or staff may video and/or audio record this course (hereby referred to as "Recordings"). By enrolling in this course, you hereby give the University of Pittsburgh and
the Institute for Clinical Research Education, through its faculty, employees, agents, licenses or assigns, the irrevocable and worldwide right to use your name, voice, likeness and/or image in all forms and media (to include internet websites and online course website). You waive your right to inspect or approve the finished version(s) of the Recordings, including any copy that may be created in connection therewith. You understand that you will not be paid for your participation in the Recording and that you are not entitled to your own copy of the Recording. You understand that the University of Pittsburgh is not responsible for any unauthorized use of the Recording. You have read this syllabus and have no questions about the contents, and you are an adult over the age of 18.

Student-Produced Recordings: To ensure the free and open discussion of ideas, students may not record classroom lectures, discussion and/or activities without advance written permission of the instructor. Any such recording properly approved in advance can be used solely for the student’s own private use.

Academic Integrity
You are expected to comply with the University of Pittsburgh’s Policy on Academic Integrity detailed here: http://www.provost.pitt.edu/info/ai1.html. Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University Policy. Furthermore, no student may bring any unauthorized materials to an exam, including dictionaries and programmable calculators.

Disabilities
If you have a disability for which you are requesting an accommodation, you are encouraged to contact both your instructor and the Office of Disability Resources and Services, 216 William Pitt Union, 412-648-7890 / 412-3837355 (TTY), as early as possible in the term. Disability Resources and Services will verify your disability and determine reasonable accommodations for this course.

Competencies Addressed in This Course

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<tr>
<th>Competency</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
<th>M4</th>
<th>M5</th>
<th>M6</th>
<th>M7</th>
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<td>Written Communication: Write about research and findings for a range of audiences, and respond in writing to constructive criticism and questions.</td>
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<td>Oral Communication: Prepare and deliver oral presentations of research at a variety of stages to a range of audiences, and respond to constructive criticism and questions.</td>
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<td>Multidisciplinary Teamwork: Demonstrate behaviors necessary to be an effective member of a multidisciplinary team.</td>
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<td>Multidisciplinary Teamwork: Engage in self-assessment, recognizing and addressing strengths and weaknesses in your research skills.</td>
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<td>Measurement: Identify basic reliability and validity issues of various measuring instruments.</td>
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<td>Measurement</td>
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<td>Address cultural diversity issues when selecting or adapting measurement instruments.</td>
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<td>Describe the characteristics underlying data quality and your ability to answer clinical or translational research problems.</td>
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Module 1: Key Steps in the Measurement Process

At the conclusion of this module, you should be able to:

- Discuss categories of variables and level of measurement
- Discuss sources of error in measurement
- Gain an understanding for “where you begin” in development, modification, or selection of measures for clinical research

Topics:

- Introduction to the course and course content
- Building a conceptual model
- Operationalizing key variables
- Selecting measures and gathering data

Before coming to class:

- Watch assigned videos, take notes, write down questions
- Read the following articles:

Module 2: Face and Content Validity

At the conclusion of this module, you should be able to:

- Define and distinguish face and content validity
- Describe the importance of content validity and why and when an investigator should address content validity
- Explain the systematic ways to assess content validity

Topics

- Items and clinical indicators that operationalize a concept
- Data supporting content validity

Complete the following:

- Watch assigned videos, take notes, write down questions
- Read the following articles:
Module 3: Reliability Overview and Rater Reliability

At the conclusion of this module, you should be able to:

- Define reliability and its relationship with measurement error
- Distinguish between inter- and intra-rater reliability
- Calculate rater reliability using multiple statistics (e.g., percent agreement, Kappa)
- Determine the appropriate rater reliability statistic based on level of measurement and number of raters

Topics

- Inter-rater reliability
- Intra-rater reliability

Before coming to class:

- Watch assigned videos, take notes, write down questions
- Read the following articles:

Due by 8:30 a.m. today: Assignment 2
Module 4: Reliability across Time, Measurement Versions, and Indicators

At the conclusion of this module, you should be able to:
- Describe the full range of reliability evidence for a measure
- Identify potential sources of low and/or inadequate reliability
- Calculate and interpret coefficient alpha

Topics
- Test-retest reliability
- Parallel/alternate form reliability
- Internal consistency reliability

Complete the following:
- Watch assigned videos, take notes, write down questions
- Read the following articles:

Module 5: Validity Overview, Criterion Validity, and Construct Validity

At the conclusion of this module, you should be able to:
- Name and describe the various types of validity evidence
- Discuss different types of validity such as face content, criterion and construct
- Address key questions such as whether the validity evidence for a particular measure is adequate

Topics
- Criterion validity
- Construct validity

Before coming to class:
Watch assigned videos, take notes, write down questions
- Read the following articles:
  - DeVellis. Fourth Edition. Pages 92-100

Due by 8:30 a.m. today: Assignments 3 & 4
Module 6: Validity Gold Standard and Sociodemographic Issues

At the conclusion of this module, you should be able to:
- Address validity in the context of a gold standard
- Calculate and interpret sensitivity and specificity values
- Calculate and interpret positive and negative predictive values
- Understand and interpret a ROC curve in the measurement context
- Explain the role of sociodemographics in measure selection or use

Topics
- Sensitivity and Specificity
- Positive and negative predictive values
- Responsiveness to change
- Receiver operating characteristic (ROC) curves
- Sociodemographic issues (e.g., language, ethnicity, age, socioeconomic status, and education level)

Complete the following:
- Watch assigned videos, take notes, write down questions
- Read the following articles:

Due by 8:30 a.m. today: Assignment 5
Module 7: Survey Development and Deployment, Factor Analysis

At the conclusion of this module, you should be able to:

- Describe key issues in questionnaire item development and sequencing
- Describe pros and cons of self-report data collection methods
- Describe the basic types and purpose of Factor Analysis
- Describe the key steps in Factor Analysis
- Interpret factor analytic output

Topics:

- Item and response option wording
- Item sequencing
- Questionnaire administration.
- Factor analysis

Before coming to class:

- Watch assigned videos, take notes, write down questions
- Read the following articles:

Module 8: Final Exam

Due by 8:30 a.m. today: Assignments 6 and 7