



1. General Information

1a. Submitted by the College of: MEDICINE

Date Submitted: 2/3/2016

1b. Department/Division: Behavioral Science

1c. Contact Person

Name: John F Wilson

Email: jfwilson@uky.edu

Phone: 3236257

Responsible Faculty ID (if different from Contact)

Name:

Email:

Phone:

1d. Requested Effective Date: Semester following approval

1e. Should this course be a UK Core Course? No

2. Designation and Description of Proposed Course

2a. Will this course also be offered through Distance Learning?: Yes 4

2b. Prefix and Number: BSC 625

2c. Full Title: Fundamentals of Biostatistics for Clinical and Translational Science

2d. Transcript Title: Biostats for Clin. and Translational Science

2e. Cross-listing:

2f. Meeting Patterns

LECTURE: 1

DISCUSSION: 2

OTHER: 0

OTHEREXPLAIN: Multiple hybrid versions proposed - please see syllabi document

2g. Grading System: Letter (A, B, C, etc.)

2h. Number of credit hours: 3

2i. Is this course repeatable for additional credit? No

If Yes: Maximum number of credit hours:

If Yes: Will this course allow multiple registrations during the same semester?

New Course Report



- 2j. Course Description for Bulletin: This course is designed to support clinical and translational science students in acquiring an applied understanding of the biostatistical tools and techniques commonly used in the conduct of clinical and translational science research. Through a combination of lectures, readings, demonstrations, discussions, and self-study modules, students will understand and appreciate measurement and statistical challenges that are common to clinical and translational science. Study design, selection of independent and dependent variables, and the selection and use of statistical techniques will be the focus of the course. The course activities are intended to promote the application of biostatistics to research concepts in the students' areas of interest and to foster practical knowledge that supports students' own research agendas. If the course is listed as section 001, the format of the course is a standard lecture/discussion. If the course is listed as section 002 the format of the course is a hybrid, with approximately 50% in the classroom and 50% in an on-line format.
- **2k.** Prerequisites, if any: This course is designed primarily for graduate students pursuing research training in clinical and translational science and who have been admitted to the Clinical and Translational Science training program. All students need permission of the instructor to enroll in this course.
- 21. Supplementary Teaching Component:
- Will this course taught off campus? No If YES, enter the off campus address:
- 4. Frequency of Course Offering: Spring,

Will the course be offered every year?: Yes

If No, explain:

- 5. Are facilities and personnel necessary for the proposed new course available?: Yes If No, explain:
- 6. What enrollment (per section per semester) may reasonably be expected?: 10
- 7. Anticipated Student Demand

Will this course serve students primarily within the degree program?: Yes

Will it be of interest to a significant number of students outside the degree pgm?: No

If Yes, explain:

- 8. Check the category most applicable to this course: Relatively New Now Being Widely Established, If No, explain:
- 9. Course Relationship to Program(s).
 - a. Is this course part of a proposed new program?: No

If YES, name the proposed new program:

b. Will this course be a new requirement for ANY program?: No

If YES, list affected programs:





- 10. Information to be Placed on Syllabus.
 - a. Is the course 400G or 5007: No
- b. The syllabus, including course description, student learning outcomes, and grading policies (and 400G-/500-level grading differentiation if applicable, from **10.a** above) are attached: Yes

Distance Learning Form

Instructor Name: John F. Wilson

Instructor Email: jfwilson@uky.edu

Internet/Web-based: No

Interactive Video: No

Hybrid: Yes

- 1.How does this course provide for timely and appropriate interaction between students and faculty and among students? Does the course syllabus conform to University Senate Syllabus Guidelines, specifically the Distance Learning Considerations? The course provides approximately 2/3 time spent viewing podcasts of lectures and working through online data analysis exercises. Approximately 1/3 time is spent in in-class discussion. The interactions between the instructor and the student in terms of assignments and feedback is similar to the more traditional pedagogy in which lectures are delivered in person. The syllabus is in accordance with university regulations.
- 2.How do you ensure that the experience for a DL student is comparable to that of a classroom-based student's experience? Aspects to explore: textbooks, course goals, assessment of student learning outcomes, etc. Learning outcomes and assessments are similar across different hybrid versions. On-line resources were created to replace inclass material. The format essentially flips the content delivery to occur outside of class, freeing more time for discussion.
- 3.How is the integrity of student work ensured? Please speak to aspects such as password-protected course portals, proctors for exams at interactive video sites; academic offense policy; etc. Both the in-classroom format of this class and the hybrid format use exactly the same canvas portals and has the same academic offense policies. There are no on-line examinations requiring proctoring.
- 4.Will offering this course via DL result in at least 25% or at least 50% (based on total credit hours required for completion) of a degree program being offered via any form of DL, as defined above? no

If yes, which percentage, and which program(s)? no

- 5.How are students taking the course via DL assured of equivalent access to student services, similar to that of a student taking the class in a traditional classroom setting? This is a graduate class involving ten or fewer students. Access to the instructor in either format is readily available and occurs regularly due to the regular submission of assignments and receipt of feedback about those assignments.
- **6.How do course requirements ensure that students make appropriate use of learning resources?** Equal access on CANVAS to course materials.
- 7.Please explain specifically how access is provided to laboratories, facilities, and equipment appropriate to the course or program. Individual mentorship regarding the student's own research occurs regularly in both the traditional and hybrid formats. Faacilities is not an issue for either course.

New Course Report



8.How are students informed of procedures for resolving technical complaints? Does the syllabus list the entities available to offer technical help with the delivery and/or receipt of the course, such as the Information Technology Customer Service Center (http://www.uky.edu/UKIT/)? Technical resources are listed for both syllabi related to CANVAS access, availability of statistical packages, and access to advice from instructors.

9.Will the course be delivered via services available through the Distance Learning Program (DLP) and the Academic Technology Group (ATL)? NO

If no, explain how student enrolled in DL courses are able to use the technology employed, as well as how students will be provided with assistance in using said technology. CANVAS based resources.

- 10.Does the syllabus contain all the required components? YES
- 11.I, the instructor of record, have read and understood all of the university-level statements regarding DL.

Instructor Name: John F. Wilson

SIGNATURE|CLEUKEF|Carl G Leukefeld|BSC 625 NEW Dept Review|20151104

SIGNATURE|DDBEAT1|Dorcas D Beatty|BSC 625 NEW College Review|20160106

SIGNATURE|ZNNIKO0|Roshan N Nikou|BSC 625 NEW Graduate Council Review|20160129

SIGNATURE|JEL224|Janie S Ellis|BSC 625 NEW Senate Council Review|20160203

SIGNATURE|CLEUKEF|Carl G Leukefeld|BSC 625 NEW Approval Returned to Dept|20160209

SIGNATURE|JEL224|Janie S Ellis|BSC 625 NEW Senate Council Review|20160224

SIGNATURE|CLEUKEF|Carl G Leukefeld|BSC 625 NEW Approval Returned to Dept|20160225

New Course Form

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	(*deno	otes required fields)			
1. General Information					
a. * Submitted by the College of: MEDICINE		Submission Date:	2/3/2016	İ	
b. * Department/Division: Behavioral Scie	итсө	T i			
c.					- ,
* Contact Person Name:	John F Wilson	Email: jfwilson@uky.edu	Phone: 3	236257	_
* Responsible Faculty ID (if different from	Contact)	Email:	Phone:		1
d. * Requested Effective Date: 🏻 🎱 Semester	following approval OR 🖰 Spe	cific Term/Year ^L			
e. '					
Should this course be a UK Core Course?	○Yes ® No				
If YES, check the areas that apply:					
Inquiry - Arts & Creativity	Composition & Communication	ions - II	•		
☐ Inquiry - Humanities	Quantitative Foundations				
Inquiry - Nat/Math/Phys Sci	Statistical Inferential Reason	ning			
Inquiry - Social Sciences	U.S. Citizenship, Community	y, Diversity			
Composition & Communications - I	Global Dynamics				
*					
2. Designation and Description of Proposed Cou	•				
a. * Will this course also be offered through D	oistance Learning?	No			
b. * Prefix and Number: BSC 625		**			
c. * Full Title: Fundamentals of Biostatisti	cs for Clinical and Translation	al Science			
d. Transcript Title (if full title is more than 40	characters): Biostats for Clin.	and Translational Science			
e. To be Cross-Listed ² with (Prefix and Numb	er);				
f. * Courses must be described by at least on	e of the meeting natterns below	v. Enclude number of actual cont	act hours ³ for ea	ach meeting pattern type	
1 Lecture	Laboratory ¹	Recitation		2 Discuss	
Indep. Study	Clinical	Colloquium	ì	Practic	nusi
Research	Residency	Seminar		Studio	
0 Other	If Other, Please explain:	Multiple hybrid v	ersions propos	ed - please see syllabi	docume
g. * Identify a grading system:					
(A) Letter (A, B, C, etc.)					
O Pass/Fail					
Medicine Numeric Grade (Non-medical s Graduate School Grade Scale	students will receive a letter gra	de)			
A Granuate School Grade Scale					
h. * Number of credits: 3	:				

	This course is designed to support clinical and translational science students in acquiring an applied understanding of the biostatistical tools and techniques commonly used in the conduct of clinical and translational science research. Through a combination of lectures, readings, demonstrations, discussions, and self-study modules, students will understand and appreciate measurement and statistical challenges that are common to clinical and translational science. Study design, selection of independent and dependent variables, and the selection and use of statistical techniques will be the focus of the course. The course activities are intended to promote the application of biostatistics to research concepts in the students' areas of interest and to foster practical knowledge that supports students' own research agendas. If the course is listed as section 001, the format of the course is a standard lecture/discussion. If the course is listed as section 002 the format of the course is a hybrid, with approximately 50% in the classroom and 50% in an on-line format.
	k. Prerequisites, if any: This course is designed primarily for graduate students pursuing research training in clinical and translational science and who have been admitted to the Clinical and Translational Science training program. All students need permission of the instructor to enroll in this course.
	·
	I. Supplementary teaching component, if any: ○ Community-Based Experience ○ Service Learning ○ Both
	Will this course be taught off campus? ① Yes ⑨ No YES, enter the off campus address:
. F	requency of Course Offering.
•	a. * Course will be offered (check all that apply): Pall Spring Summer Winter Win
	b. * Will the course be offered every year?
	If No, explain:
. *	Are facilities and personnel necessary for the proposed new course available?
	No, explain:
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i	
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. *	What enrollment (per section per semester) may reasonably be expected?
. А	nticipated Student Demand.
	a. * Will this course serve students primarily within the degree program?
	b. * Will it be of interest to a significant number of students outside the degree pgm? ①Yes @ No
	If YES, explain:
. *	Check the category most applicable to this course:
	Traditional - Offered in Corresponding Departments at Universities Elsewhere
_	Zirelatively New - Now Being Widely Established Not Yet Found in Many (or Any) Other Universities
	ourse Relationship to Program(s).
	a. * Is this course part of a proposed new program?
	b. * Will this course be a new requirement * for ANY program? O Yes O No
	If YES ⁵ , list affected programs::
	of country and the file and the file later.
, I	nformation to be Placed on Syllabus.
	 a. * Is the course 400G or 500? Yes No
	b. The syllabus, including course description, student learning outcomes, and grading policies (and 400G-/500-level grading differentiation if applicable, from 10 attached.
	Distance Learning Form
is fo	rm must accompany every submission of a new/change course form that requests distance learning delivery. This form may be required when changing a course already approved for DL

Introduction/Definition: For the purposes of the Commission on Colleges Southern Association of Colleges and Schools accreditation review, distance learning is defined as a foreducational process in which the majority of the instruction (interaction between students and instructors and among students) in a course occurs when students and instructors the same place. Instruction may be synchronous or asynchronous. A distance learning (DL) course may employ correspondence study, or audio, video, or computer technologies

A number of specific requirements are listed for DL courses. The department proposing the change in delivery method is responsible for ensuring that the requirement are satisfied at the individual course level. It is the responsibility of the instructor to have read and understood the university-level assurances regarding an equivalent expestudents utilizing DL (available at http://www.ukv.edu/USC/New/forms.htm).

							·
Cours	e Number and Prefix:	BSC625		_	Date;	10/30/2015	
Instru	ictor Name:	John F. Wilson		_	Instructor Email:	jfwilson@uky.edu	
Check	the method below that	best reflects how the					
			Internet/We	eb-based □	Interactive Video	Hybrid 🗹	
urricul	um and Instruction						
1 Ho	w does this course prov	ride for timely and an	propriate intera	tion hetween st	udents and faculty and am	ong students? Does the course syllat	ous conform to University
	flabus Guidelines, specii				addition and income, and ann	ong stadentar boes the tourse synar	as comorn to omircially
					ng podcasts of lect n in-class discuss:	ures and working through of ion. The interactions be	
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	•	,	student is com	parable to that	of a classroom-based stude	ent's experience? Aspects to explore:	textbooks, course goals,
	student learning outcomes		are simila	ar across di	fferent hybrid ver	sions. On-line resources	were created to
						very to occur outside of a	
	w is the integrity of studicy; etc.	dent work ensured? P	lease speak to a	spects such as	password-protected course	portals, proctors for exams at intera	ctive video sites; academ
Вс	th the in-classr				id format use exac examinations requir	tly the same canvas portal	s and has the
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	ll offering this course vi defined above?	a OL result in at feast	25% or at least	: 50%* (based o	on total credit hours require	ed for completion) of a degree progra	ım being offered via any f
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Wh no	aich percentage, and wh	ich program(s)?					
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	s a general rule, if appro- onths from the date of a		L delivery result	is in 50% or moi	e of a program being deliv	ered through DL, the effective date of	if the course's DŁ delivery
5 Hor	w are students taking ti	he course via DL assu	red of equivaler	at access to stud	ent services, similar to the	t of a student taking the class in a tr	aditional classmom settini
	nis is a graduate					instructor in either form	
av	vailable and occu	rs reguolarly d	iue to the 1	regular subm	ission of assignmen	nts and receipt of feedbac	k about those
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(e)	No						
Ifr	no, explain how students	s enrolled in DL course	es are able to u	se the technolog	y employed, as well as how	w students will be provided with assis	stance in using said techn
CA	NVAS based resou	rces.	,				
10. Do	es the syllabus contain a	all the required compo	onents, below?[Yes			
	· Instructor's virtual	office hours, if any.					2
	The technological re	equirements for the co	ourse.				
		n for Distance Learning du/UKIT/Help/; 859-2		o://www.uky.ed	u/DistanceLearning) and Ir	nformation Technology Customer Ser	vice Center
	Procedure for resolutions						
	Preferred method for	-		ne, text messar	ie.		
	Maximum timefram			-	ı =-		
		a academic accommo					

- "If you have a documented disability that requires academic accommodations in this course, please make your request to the University Disability Resource. The Center will require current disability documentation. When accommodations are approved, the Center will provide me with a Letter of Accommodation details the recommended accommodations. Contact the Disability Resource Center, Jake Karnes, Director at 859-257-2754 or jkarnes@emāil.uky.edu."
- Specific dates of face-to-face or synchronous class meetings, if any.
- Information on Distance Learning Library Services (http://www.eky.edu/Libraries/DLLS)
 - Carla Cantagallo, DL Librarian
 - Local phone number: 859 257-0500, ext. 2171; long-distance phone number: (800) 828-0439 (option #6)
 - Email: dlservice@email.ukv.edu
 - DL Interlibrary Loan Service; http://www.ukv.edu/Libraries/libpage.php?lweb_id=253&llib_id=16

11.	I, the instructor of record, have read and understood all of the university-level statements regarding DL
	Instructor Mame

John F. Wilson

Abbreviations: DLP = Distance Learning Programs ATG = Academic Technology Group Customer Service Center = 859-218-HELP (http://www.ukv.edu/UKIT/Help)

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(II) Courses are typically made effective for the semester following approval. No course will be made effective until all approvals are received.

[21] The chair of the cross-listing department must sign off on the Signature Routing Log.

11 In general, undergraduate courses are developed on the principle that one semester hour of credit represents one hour of classroom meeting per week for a semester, exclusive of any laboratory meeting. La meeting, generally, represents at least two hours per week for a semester for one credit hour. (from SR 5.2.1)

141 You must also submit the Distance Learning Form in order for the proposed course to be considered for DL delivery.

 $\underline{^{\text{ISI}}}$ in order to change a program, a program change form must also be submitted,

Rev 8/09

Two sample syllabi for the new course are provided below. BSC625 is being submitted as a departmental course providing instruction in the application of biostatistical techniques to research topics on clinical and translational science. It is intended for graduate students accepted into the clinical and translational science certificate and degree programs. Our intent is to provide a mixture of hybrid and traditional graduate course pedagogies that will meet the needs of students with a variety of backgrounds. Many clinical and translational science students are working M.D. professionals for whom a hybrid format that combines inclass discussion with on-line materials provides the best opportunity for learning. Some students prefer a course with more in-class lectures and discussion. This will be a departmental course taught by different instructors in different semesters and years. We are submitting the course so that the pedagogical approach can range from primarily inclass lecture and discussion to a varying mix of on-line video and data analysis exercises and in-class discussion. Only the pedagogical approach varies. The learning outcomes are the same. We are asking approval for both distance and non-distance learning approaches. The pedagogical approaches illustrated in these syllabi have been piloted by BSC faculty Jennifer Havens and Matt Webster using a departmental special topics course (BSC772) or an independent study (BSC790) course. Dr. Wilson is submitting the course application on behalf of the BSC faculty as the chair of the department's curriculum committee and the Associate Chair for Education in the Department of Behavioral Science.

Sample Syllabus 1: Primarily In-class lecture and discussion

BSC625 Fundamentals of Biostatistics for Clinical and Translational Research Tuesdays 5:00 - 7:30

Instructor:

Jennifer Havens, M.P.H., Ph.D.

Office Address: Email: 845 Angliana, 40508 jhave2@uky.edu

Office Phone:

Office hours: T

TBA

Course Description

This course is designed to support clinical and translational science students in acquiring an applied understanding of the biostatistical tools and techniques commonly used in the conduct of clinical and translational science research. Through a combination of lectures, readings, demonstrations, discussions, and self-study modules, students will understand and appreciate measurement and statistical challenges that are common to clinical and translational science. Study design, selection of independent and dependent variables, and the selection and use of statistical techniques will be the focus of the course. The course activities are intended to promote the application of biostatistics to research concepts in the students' areas of interest and to foster practical knowledge that supports students' own research agendas.

Prerequisites

This course is designed primarily for graduate students pursuing research training in clinical and translational science who have been admitted to the CTSC training program. All students need permission of the instructor.

Student Learning Outcomes

After completion of this course, students will be able to:

- 1. Determine the appropriate study design for a given research question.
- 2. Determine the distribution of a variable and select the most appropriate statistical technique based on that distribution.
- 3. Conduct bivariate analyses and recognize when it is appropriate to utilize multivariate analyses.
- 4. Critically analyze extant research articles to determine whether the appropriate statistical techniques were utilized.
- 5. Conduct multivariate analyses.

Course Materials

Course materials are on the CANVAS site. Materials include video lectures, readings, and application activities. It is the student's responsibility to check the CANVAS site for the week's activities. Course materials include PowerPoint slides from lectures, independent study modules, and sample datasets for simulation analyses. Students will be expected to become familiar with a statistical computing package. In class demonstrations will use STATA, Version 13.0, but students may use other packages such as SPSS or SAS. THERE IS NO REQUIRED TEXT FOR THE COURSE.

Library Services: Campus-based students can also contact the Young Library for assistance at 859-218-2048 (voice), 859-904-2733 (text via SMS), refdesk@uky.edu (email), or http://libanswers.uky.edu (internet). Distance learning students who desire library assistance may contact Carla Cantagallo at 859-257-0550, ext. 2171, dllservice@uky.edu or visit http://libraries.uky.edu/dlls.

Course Activities and Expectations

Learning will be facilitated through a combination of lectures and hands-on analyses, written activities and group discussions. These activities include:

- 1) Analytic Plans and Results. After the completion of each lecture, students will be expected to propose a research question, hypotheses, analytic plan, complete an analysis and write up the results for one of the statistical techniques that were presented that day using the datasets provided by the course directors. The one to two paragraph write-up (AND ACCOMPANYING LOG) will be due by 5 pm on the Saturday after class and is to be uploaded to the individual students' dropbox folder. In addition, all Stata (or other statistical program) output must be included with the write-up. IF YOU DO NOT MAKE PREVIOUS ARRANGEMENTS (before Saturday at 5) AND YOUR ASSIGNMENT IS NOT IN YOUR FOLDER, YOU WILL RECEIVE A ZERO FOR THAT ASSIGNMENT.
- 2) Exams. There will be three exams throughout the course. These exams are designed to determine the students' comprehension of the statistical techniques presented. Exams will NOT test your knowledge of the statistical *program*, but the statistical *concepts*. The exams are NOT cumulative; however, since the course builds upon concepts previously discussed, material presented in previous lectures may appear as part of a problem. You will be allowed to consult all course materials during the exam and the exam will be pass/fail with a passing grade being 80%. For Exams 1 and 2, if you receive an 80% or above, you will receive full credit (100 points) for the exam. If you do not achieve at least an 80% on the exam, you will have the opportunity to correct your errors. If corrected, I will regrade the entire exam and you will receive that numeric grade as opposed to 100 points. For the FINAL exam, you will receive a numeric grade from 0-100. IF YOU ARE GOING TO MISS AN EXAM, PLEASE MAKE ARRANGEMENTS PRIOR TO THE EXAM DATE. IF YOU DO NOT INFORM ME THAT YOU WILL BE MISSING THE EXAM YOU WILL RECEIVE A ZERO FOR THAT EXAM.

Grading for the Course

Points will be accumulated for completion of the required elements of the course at an acceptable level of quality. In general, it is the course directors' grading philosophy to allocate the full point value as long as reasonable effort has been directed towards a given activity; sloppy or incomplete work, however, will be penalized at the discretion of the course directors. While attendance is not mandatory, we will be building upon concepts from class to class.

Maximum point values for course activities are as follows:

Weekly Assignments (Analytic): 8 @ 25 points each = 200 possible points Exams: 3 @ 100 points each = 300 possible points

Based on your accumulation of points, your grade will be calculated as follows:

A: 90-100% equivalent to 450 - 500 course points B: 80-89% equivalent to 400 - 449 course points

C: 70-79% equivalent to 350 - 399 course points

E <70% equivalent to <300 course points

Detailed Outline of Topics and Activities for the Course

WEEK 1:

Class meets for Topic 1, "Introduction to the Course"

During this meeting we will discuss course expectations, student's primary research interest/area of specialty and previous statistics training (if any), and have a <u>brief</u> demonstration of the course format.

WEEK 2:

Class meets for Topic 2, "Study Design"

During this meeting we will first begin to explore STATA, examine the types of studies that are conducted as a part of clinical and translation science, as well as study the types of variables we will often be confronted with, paying special attention to the statistical implications for each type of variable and study design.

DUE SATURDAY following week 2 class BY 5:00 PM:

1) Analytic assignment (open STATA, begin a log, open a file, describe dataset, and summarize one variable). Upload this log only (no write-up). Dataset in class dropbox folder. Datasets\Assignments\Week2.dta

WEEK 3:

Class meets for Topic 3, "Data Distribution and Development of Hypotheses" During this meeting we will discuss research questions, hypotheses and distribution of data. We will also examine how to visualize variable distribution in STATA.

DUE SATURDAY following class BY 5:00 PM:

1) Methods and results paragraph (given the assigned dataset

[Datasets\Assignments\Week3.dta]). First, open a log, then identify the variable that correlates with each of the distributions discussed in lecture (continuous, binomial, multinomial and Poisson). Cut and paste each variable with the corresponding graphic you used to identify the distribution into a word file. Next, using this simple dataset (or your own), formulate a research question, hypothesis (null and alternative hypothesis), identify the variables you would utilize to test this hypothesis. One paragraph will include the research question and hypothesis and the other will include the "methods" (the variables [dependent and independent] you chose to test the hypothesis and the distribution of those variables).

WEEK 4:

Class meets for Topic 4, "Measures of Central Tendency"

During this meeting we will discuss measures of central tendency (mean, median, and mode).

DUE SATURDAY following class BY 5:00 PM:

1) Methods and results paragraph - Using the dataset Week4.dta in the Assignment Folder (Datasets\Assignments\Week4.dta), formulate a research question and hypothesis (null and alternative hypothesis). Your first paragraph will include the research question and hypothesis and the other will include the "methods" (the variables [dependent and independent] you chose to test the hypothesis, the distribution of your dependent variable, whether it is normally distributed, and the mean and median of you dependent variable). Finally, a statement should be made about whether the mean or median should be presented and why.

<u>WEEK 5:</u>

Class meets for Exam 1 and Topic 5, "Hypothesis Testing for Continuous Variables"

We wills start with the exam, then move to the lecture. During this meeting we will discuss how to test hypotheses for data with various distributions (normal and non-normal). Both parametric and non-parametric tests will be examined as well as both bivariate and multivariate statistics for variables with continuous distributions.

DUE SATURDAY following class BY 5:00 PM:

1) Methods and results paragraph. Using the dataset Week5.dta in the Assignment Folder (Datasets\Assignments\Week5.dta), formulate a research question and hypothesis (null and alternative hypothesis). Your first paragraph will include the research question and hypothesis and the

other will include the "methods" (the variables [dependent and independent] you chose to test the hypothesis, the distribution of your dependent variable, whether it is normally distributed, and the test that should be utilized to determine association with independent variables. A linear regression should also be attempted with at least one independent variable.

WEEK 6:

Class meets for Topic 5 – Examples

In this class, we will first go over the exam, then go over detailed examples of hypothesis testing for continuous variables.

WEEK 7:

Class meets for Topic 6, "Hypothesis Testing for Dichotomous/Categorical Variables"

During this meeting we will discuss how to test hypotheses for data with dichotomous or categorical outcomes. Both parametric and non-parametric tests will be examined as well as both bivariate and multivariate statistics for variables with dichotomous or categorical distributions.

Examples of analyses utilizing logistic and other multivariate regression techniques will be presented.

DUE SATURDAY following class BY 5:00 PM:

1) Methods and results paragraph – Week7.dta in the Assignment Folder (Datasets\Assignments\Week7.dta), formulate a research question and hypothesis (null and alternative hypothesis). Your first paragraph will include the research question and hypothesis and the other will include the "methods" (the variables [dependent and independent] you chose to test the hypothesis, the distribution of your dependent variable, and the test that should be utilized to determine association with independent variables. A logistic regression should also be attempted with at least one independent variable.

UK Spring Break NO CLASS

WEEK 8:

Class meets for Topic 7, "Hypothesis Testing for Correlated Data" + Examples.
We will discuss how to test hypotheses for correlated data with various distributions (normal and non-normal). Both parametric and non-parametric tests will be examined

as well as bivariate statistics for correlated data (ANOVA, McNemar, etc).

DUE SATURDAY following class BY 5:00 PM:

1) Methods and results paragraph – Week9.dta in the Assignment Folder (Datasets\Assignments\Week9.dta), formulate a research question and hypothesis (null and alternative hypothesis). Your first paragraph will include the research question and hypothesis and the other will include the "methods" (the variables [dependent and independent] you chose to test the hypothesis, the distribution of your dependent variable, and the test that should be utilized to determine association with independent variables.

WEEK 9: - Fayette County Spring Break NO CLASS

WEEK 10:

Class meets for Class meets for Topic 8, "Hypothesis Testing for Ordered/Multinomial Outcomes"

We will discuss how to test hypotheses for categorial data that are ordered or not. Both parametric and non-parametric tests will be examined as well as bivariate and multivariate statistics for ordered and multinomial outcomes.

DUE SATURDAY following class BY 5:00 PM:

1) Methods and results paragraph – Week9.dta in the Assignment Folder (Datasets\Assignments\Week9.dta), formulate a research question and hypothesis (null and alternative hypothesis). Your first paragraph will include the research question and hypothesis and the other will include the "methods" (the variables [dependent and independent] you chose to test the hypothesis, the distribution of your dependent variable, and the test that should be utilized to determine association with independent variables. SEE LECTURE NOTES FOR MORE DETAILED EXPLANATION OF ASSIGNMENT.

WEEK 11:

Class meets for Topic 8 – Examples

In this class, we will go over detailed examples of hypothesis testing for ordered and multinomial outcomes.

WEEK 12:

Class meets for Exam 2

Week 13:

Class meets for Class meets for Topic 9, "Hypothesis Testing for Rates and Counts"

During this meeting we will discuss hypothesis testing for rates and counts with examples. In addition, the final exam will be presented.

DUE FRIDAY BY 5:00 PM:

1) Methods and results paragraph – Week9.dta in the Assignment Folder (Datasets\Assignments\Week9.dta), formulate a research question and hypothesis (null and alternative hypothesis). Your first paragraph will include the research question and hypothesis and the other will include the "methods" (the variables [dependent and independent] you chose to test the hypothesis, the distribution of your dependent variable, and the test that should be utilized to determine association with independent variables. SEE LECTURE NOTES FOR MORE DETAILED EXPLANATION OF ASSIGNMENT.

Week 14:

Due date for FINAL EXAM

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Incompletes -

The student should understand that a grade of incomplete (I) is given at the discretion of the instructor. Such a grade will only be assigned under extenuating circumstances and will not be given because the student did not have time to complete the assignments. If a grade of incomplete is assigned, in accordance with university policy, the student will have one year to complete the class assignments. No extensions will be granted.

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Plagiarism includes reproducing someone else's work (including, but not limited to a published article, a book, a website, computer code, or a paper from a friend) without clear attribution. Plagiarism also includes the practice of employing or allowing another person to alter or revise the work, which a student submits as his/her own, whoever that other person may be. Students may discuss assignments among themselves or with an instructor or tutor, but when the actual work is done, it must be done by the student, and the student alone.

When a student's assignment involves research in outside sources or information, the student must carefully acknowledge exactly what, where and how he/she has employed them. If the words of someone else are used, the student must put quotation marks around the passage in question and add an appropriate indication of its origin. Making simple changes while leaving the organization, content, and phraseology intact is plagiaristic. However, nothing in these Rules shall apply to those ideas, which are so generally and freely circulated as to be a part of the public domain.

Please note: Any assignment you turn in may be submitted to an electronic database to check for plagiarism.

Accommodations due to disability

If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (DRC). The DRC coordinates campus disability services available to students with disabilities. It is located on the corner of Rose Street

and Huguelet Drive in the Multidisciplinary Science Building, Suite 407. You can reach them via phone at (859) 257-2754 and via email at drc@uky.edu. Their web address is http://www.uky.edu/StudentAffairs/DisabilityResourceCenter/.

Sample Syllabus 2: (Approximately 50% On-line, 50% in-class discussion

BSC625

Fundamentals of Biostatistics for Clinical and Translational Research Wednesday 5:00-7:30

Instructor:

Matt Webster, Ph.D.

Office Address:

Medical Behavioral Science Building

Email:

matt.webster@uky.edu (preferred contact with instructor, response

within 24 hours)

Office Phone:

859 323 6257

Office hours:

To be arranged

Course Description

This course is designed to support clinical and translational science students in acquiring an applied understanding of the biostatistical tools and techniques commonly used in the conduct of clinical and translational science research. Through a combination of lectures, readings, demonstrations, discussions, and self-study modules, students will understand and appreciate measurement and statistical challenges that are common to clinical and translational science. Study design, selection of independent and dependent variables, and the selection and use of statistical techniques will be the focus of the course. The course activities are intended to promote the application of biostatistics to research concepts in the students' areas of interest and to foster practical knowledge that supports students' own research agendas.

Prerequisites

This course is designed primarily for graduate students pursuing research training in clinical and translational science who have been admitted to the CTSC training program. All students need permission of the instructor.

Student Learning Outcomes

After completion of this course, students will be able to:

- 1. Determine the appropriate study design for a given research question.
- 2. Determine the distribution of a variable and select the most appropriate statistical technique based on that distribution.
- 3. Conduct bivariate analyses and recognize when it is appropriate to utilize multivariate analyses.
- 4. Critically analyze extant research articles to determine whether the appropriate statistical techniques were utilized.
- 5. Conduct multivariate analyses.

Course Materials

Course materials are on the CANVAS site. Materials include video lectures, readings, and application activities. It is the student's responsibility to check the CANVAS site for the week's activities. Although a specific statistical package is not required for the course, in-class demonstrations will be performed using SPSS. Students can download a free copy of SPSS from download uky.edu, if they would like to conduct demonstration analyses using the same program as the in-class demonstrations. Out of class exercises can be completed using any of the commonly used statistical packages (e.g. SAS, STATA, MINITAB).

<u>Library Services</u>: Distance learning students who desire library assistance may contact Carla Cantagallo at 859-257-0550, ext. 2171, <u>dllservice@uky.edu</u> or visit http://libraries.uky.edu/dlls, or email Dr. Webster matt.webster@uky.edu, who will respond within 24 hours. Campus-based students can also contact the Young Library for assistance at 859-218-2048 (voice), 859-904-2733 (text via SMS), refdesk@uky.edu (email), or http://libanswers.uky.edu (internet).

- Instructor's *virtual* office hours, (none)
- The technological requirements for the course: Computer with access to the University of Kentucky CANVAS Learning management system.

- Contact information for Distance Learning programs (http://www.uky.edu/DistanceLearning) and Information Technology Customer Service Center (http://www.uky.edu/UKIT/Help/; 859-218-HELP).
- Procedure for resolving technical complaints. Contact Dr. Webster
- Preferred method for reaching instructor: email: <u>matt.webster@uky.edu</u>

Course Activities and Expectations

Learning will be facilitated through a combination of on-line lectures, reading assignments, written application activities, and in-class demonstrations and discussion.

- 1) On-line lectures. On-line lectures will be delivered as video modules on the canvas course website. Students will be responsible for viewing these lectures during the week in which they are assigned. Online lectures will focus on specific approaches to analyzing data from practical clinical trials.
- 2) Readings. Each week, readings will be assigned. Readings are selected to reinforce and complement lecture content as well as to stimulate statistical thought processes. These readings will form the foundation for written applications.
- 3) Written Application Activities. Written application activities will provide students with the opportunity to demonstrate their understanding of lecture material and reading and to apply statistical concepts to their own area of research. For full credit, these written activities are required to be submitted on the Canvas course website by the Sunday following the weekly topic. For example, the written application activity.
- **4) In-class Demonstrations and Discussion.** In-class meetings will occur on 9/1, 9/22, 10/20, 11/10, and 12/8 from 5:00 7:30 pm in MBSB, Room 104. During inclass meetings, demonstrations of analytic approaches introduced in previous online modules will be performed in SPSS and discussion will focus on interpretation and communication of statistical results. In addition to in-class discussion, participants can initiate and/or participate in class discussions online in Canvas.
- **5) Final Exam.** The final exam will be distributed at the end of our in-class meeting On 12/8 and will be due 12/15.

Grading for the Course Points will be accumulated for completion of the required elements of the course at an acceptable level of quality. In general, it is the course directors' grading philosophy to allocate the full point value as long as reasonable effort has been directed towards a given activity; sloppy or incomplete work, however, will be penalized at the discretion of the course directors. Attendance at all inclass meetings is expected. Unexcused absence

from an in-class meeting will result in a 75 point deduction. Late submissions of written application activities will result in a 10% point penalty for the submission per day it is late.

Maximum point values for course activities are as follows:

Weekly Application Activities: 12 @ 25 points each = 300 possible points

Final Exam: 100 points

Based on your accumulation of points, your grade will be calculated as follows:

A: (90-100%) 360 - 400 points

B: (80-89%) 320 - 359 points

C: (70-79%) 280 - 319 points

E: (<70%) < or = 279 points

Outline of Topics and Activities for the Course

Note: Readings should be completed during the week in which they are assigned and prior to completing written application activities. The written application activities are due on the Sunday following the content delivery. Students will submit application activities on the Canvas course site.

WEEK 1: In-class Meeting: "Introduction to the Course"

During this meeting, we will review the course syllabus and format, demonstrate the Canvas platform, and discuss characteristics of good research questions/hypotheses.

Readings due 9/6

- Altman, D.G. (1994). The scandal of poor medical research. *British Medical Journal*, 308(6924), 283-284.
- Sprint, P. (2003). Statistics in medical research. Swiss Medical Weekly, 133, 522-529.
- West, C.P., & Ficalora, R.D. (2007). Clinician attitudes toward biostatistics. *Mayo Clinic Proceedings*, *82*(8), 939-943.

Application Activity #1 due following week

WEEK 2: Online Modules: "Hypothesis Testing and Variables"

Online modules will discuss hypothesis testing, variable measurement, and variable roles used in the analysis of practical clinical trials.

Readings due following week

- Siegfried, T. (March 27, 2010). Odds are, it's wrong. Science News. Retrieved from https://www.sciencenews.org/article/odds-are-its-wrong
- Ioannidis, J.P.A. (2005). Why most published research findings are false. *PLOS Medicine*, *2*(8), e124.
- Sterne, J., & Smith, G.D. (2001). Sifting the evidence—what's wrong with

significance tests? Physical Therapy, 81(8), 1464-1469.

• Bornstein, M. (1994). The case for confidence intervals in controlled clinical trials. *Controlled Clinical Trials*, *15*(5), 411-428.

Application Activity #2 due following week

WEEK 3: Online Modules: "Descriptive Data Analysis"

Online modules will discuss measures of central tendency, variable distributions, and Measures of dispersion.

Readings due following week

- Little, R.J., D'Agostino, R., Cohen, M.L., Dickersin, K., Emerson, S.S., Farrar, J.T. et al. (2012). The prevention and treatment of missing data in clinical trials. *The New England Journal of Medicine*, 367(14), 1355-1360.
- Ludbrook, J. (2008). Outlying observations and missing values: How should they be handled? *Clinical and Experimental Pharmacology and Physiology*, 35, 670-678.
- Van den Broeck, J., Argeseanu Cunningham, S., Eeckels, R., & Herbst, K. (2005). Data cleaning: Detecting, diagnosing, and editing data abnormalities. *PLoS Medicine*, *2*(10), 966-970.

Application Activity #3 due following week

WEEK 4:

In-class Meeting: "Descriptive Data Analysis in SPSS"

During this meeting, we will discuss the previous weeks' application activities, conduct descriptive analyses in SPSS, review SPSS output, and demonstrate data cleaning.

Readings due this week

- Altman D.G., Gore, S.M., Gardner, M.J., & Popock, S.J. (1983). Statistical guidelines for contributors to medical journals. *British Medical Journal*, 286,1489-1493.
- Durbin, C.G. (2004). Effective use of tables and figures in abstracts, presentation, and papers. *Respiratory Care*, 49(10), 1233-1237.
- Cooper, R.J., Wears, R.L., & Schriger, D.L. (2003). Reporting research results: recommendations for improving communication. *Annals of Emergency Medicine*, *41*(4), 561-564.

Application Activity #4 due following week

WEEK 5: Online Modules: "Comparing Two Groups on a Continuous DV" Online modules will focus on t-tests, confidence intervals, and effect sizes.

Readings due following week

• Sullivan, G.M., & Feinn, R. (2012). Using effect size—or why the p value is not enough. *Journal of Graduate Medical Education*, 279-282.

- Kraemer, H. C., & Kupfer, D.J. (2006). Size of treatment effects and their importance to clinical research and practice. *Biological Psychiatry*, *59*, 990-996.
- Revicki, D., Hays, R.D., Cella, D., & Sloan, J. (2008). Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *Journal of Clinical Epidemiology*, *61*(2), 102-109.

Application Activity #5 due following week

WEEK 6: Online Modules: "Comparing Two Groups on a Categorical DV"
Online modules will discuss chi-square test, Fisher's exact test, McNemar test, and contingency tables.

Readings

- Schmidt, CO, & Kohlmann, T. (2008). When to use the odds ratio or the relative risk? *International Journal of Public Health*, *53*, 165-167.
- Schechtman, E. (2002). Odds ratio, relative risk, absolute risk reduction, and the number needed to treat—which of these should we use? *Value in Health*, 5(5), 431-436.
- Kent, L.M., Morton, D.P., Rankin, P.M., Gobble, J.E., & Diehl, H.A. (2015). Gender differences in effectiveness of the Complete Health Improvement Program (CHIP). *Journal of Nutrition Education and Behavior, 47*(1), 44-52.

Application Activity #6 due following week

WEEK 7: Online Modules: "Comparing Three (or more) Groups"
Online modules will discuss one-way, repeated measures, and factorial analysis of variance (ANOVA).

Readings

- Millis, J.L. (1993). Data torturing. New England Journal of Medicine, 329(16), 1196-1199.
- Bender, R., & Lange, S. (2001). Adjusting for multiple testing—when and how? *Journal of Clinical Epidemiology, 54,* 343-349.
- Lagakos S.W. (2006). The challenge of subgroup analyses Reporting without distorting. *New England Journal of Medicine*, *354*(16), 1667-1669.
- Ruxton, G.D., & Beauchamp, G. (2008). Time for some a priori thinking about post hoc testing. *Behavioral Ecology*, 690-693.

Application Activity #7 due following week

WEEK 8: In-class Meeting: "Comparing Groups in SPSS"

During this meeting, we will discuss the previous weeks' application activities, conduct analyses comparing groups with continuous and categorical variables in SPSS, and review how to present these analyses.

Readings

- Spirito, A., Monti, P. M., Barnett, N. P., Colby, S. M., Sindelar, H., Rohsenow, D.J. (2004). A randomized clinical trial of a brief motivational intervention for alcohol-positive adolescents treated in an emergency department. *The Journal of Pediatrics*, 145, 396-402.
- Webster, J. M., Staton-Tindall, M., Dickson, M. F., Wilson, J. F., & Leukefeld, C. G. (2014). Twelve-month employment intervention outcomes for drug involved offenders. *American Journal of Drug and Alcohol Abuse, 40*(3), 200-205.
- Miakowski, C., Dodd, M., West, C., Schumacher, K., Paul, S.M., Tripathy, D. et al. (2004). Randomized clinical interview of the effectiveness of a self-care intervention to improve cancer pain management. *Journal of Clinical Oncology*, 22(9), 1713-1720.

Application Activity #8 due following week

WEEK 9: October 27, 2015

Online Modules: "Using a Single Variable to Predict a Continuous DV" Online modules will discuss correlation and linear regression.

Readings

- Lachin, J. M. (2000). Statistical considerations in the intent-to-treat principle. *Controlled Clinical Trials*, *21*, 167-189.
- Sanchez, M.M., & Chen, X. (2006). Choosing the analysis population in noninferiority studies: Per protocol or intent-to-treat. *Statistics in Medicine, 25,* 11-69.

Application Activity #9 due following week

WEEK 10: Online Modules: "Using Multiple Variables to Predict a Continuous DV" Online modules will discuss multiple linear regression, model building, and interactions.

Readings

- Royston, P., Altman, D.G., & Sauerbrei, W. (2006). Dichotmizing continuous predictors in multiple regression: a bad idea. *Statistics in Medicine*, *25*, 127-141.
- Schellingerhout, J.M., Heymans, M.W., de Vet, H.C.W., Koes, B.W., & Verhagen, A.P. (2009). Catergorizing continuous variables resulted in different predictors in a prognostic model for nonspecific neck pain. *Journal of Clinical Epidemiology*, *62*, 868-874.
- Kraemer, H.C., Wilson, G.T., Fairburn, C.G., & Agras, W.S. (2002). Mediators and moderators of treatment effects in randomized clinical trials. *Archives of General Psychiatry*, *59*, 877-883.

Application Activity #10 due following week

WEEK 11: In-class Meeting: "Predicting Continuous DVs in SPSS"

During this meeting, we will discuss the previous weeks' application activities, conduct linear regression analyses in SPSS, and review how to present these analyses.

Readings

- Trenz, R., Penniman, T., Scherer, M., Zur, J., Rose, J., & Latimer, W. (2012). Problem recognition, intention to stop use, and treatment use among regular heroin injectors. *Journal of Substance Abuse Treatment*, *43*(2), 204-210.
- Nilsen, V., Bakke, P.S., Rhose, G., & Gallefoss, F. (2014). Predictors of health-related quality of life changes after lifestyle intervention in persons at risk of type 2 diabetes mellitus. *Quality of Life Research* 23(9), 2585-2593.
- Webster, J.M., Rosen, P.J., Smiley McDonald, H., Staton-Tindall, M., Garrity, T.F., & Leukefeld, C.G. (2007). Mental health as a mediator of gender differences in employment barriers among drug abusers. *The American Journal of Drug and Alcohol Abuse*, 33, 259-265.

Application Activity #11 due following week

WEEK 12: Online Modules: "Using a Single or Multiple Variables to Predict a Categorical DV" Online modules will discuss logistic regression analysis and model building.

Readings

- Clarke, J.G., Stein, L.A., Martin, R.A., Martin, S.A., Parker, D., Lopes, C.E. et al. (2013). Forced smoking abstinence: not enough for smoking cessation. JAMA Internal Medicine, 173(9), 789-794.
- Lofwall, M.R., & Havens, J.R. (2012). Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. *Drug and Alcohol Dependence*, 126(3), 379-383.
- Govani, S.M., & Higgins, P.D.R. (2012). How to read a clinical trial paper: A lesson in basic trial statistics. *Gastroenterology & Hepatology*, 8(4), 241-248.
- Lang, T. (2004). Twenty statistical errors even you can find in biomedical research articles. *Croatian Medical Journal*, 45(4), 361-370.

Application Activity #12 due next week

WEEK 13: No Course Materials - Thanksgiving

WEEK 14: Online Modules: "Other Statistical Approaches" Online modules will discuss extensions of regression analysis.

Readings

- Mosquera, R.A., Avritscher, E.B.C., Samuels, C.L., Harris, T.S., Pedroza, C. Evans, P. et al. (2014). Effect of an enhanced medical home on serious illness and cost of care among high-risk children with chronic illness: A randomized clinical trial, *JAMA*, *312*(24), 2640-2645.
- Stephens, D.B., & Havens, J.R. (2013). Predictors of alcohol use among rural

drug users after disclosure of hepatitis C virus status. *Journal of Studies on Alcohol, 74*(3), 386-395.

No Application Activity

WEEK 15: *In-class Meeting: "Predicting Categorical DVs in SPSS and Course Review"* During this meeting, we will discuss the previous weeks' application activities, conduct logistic regression analyses in SPSS, and review how to present these analyses. The second half of the class will be spent reviewing course content.

WEEK 16: December 15, 2015

Final Exam

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