Chair: Tracy Christofero | **GC#6: Course Addition**

Request for Graduate Course Addition

1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.
2. E-mail one identical PDF copy to the Graduate Council Chair. If attachments included, please merge into a single file.
3. ***The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.***

College: COHP | Dept/Division: Public Health | Alpha Designator/Number: PH 616 | (•) Graded ( ) CR/NC

Contact Person: William F. Pewen | Phone: 696-3743

NEW COURSE DATA:

New Course Title: Clinical Trials

Alpha Designator/Number: P H 6 1 6

Title Abbreviation: C l i n i c a l T r i a l s

(Limit of 25 characters and spaces)

Course Catalog Description: (Limit of 30 words)
An examination of methods and issues in conducting clinical research. Includes critical aspects of study design, protocol development, recruitment and consent, and assessment of outcomes.

Co-requisite(s): None | First Term to be Offered: Fall 2015

Prerequisite(s): PH 611, PH 621 | Credit Hours: 3

Course(s) being deleted in place of this addition (*must submit course deletion form*):

Signatures: if disapproved at any level, do not sign. Return to previous signer with recommendation attached.

Dept. Chair/Division Head [signature]	Date 3/4/15
Registrar [signature] 005122	Date 3/4/15
College Curriculum Chair [signature]	Date 3/13/15
Graduate Council Chair	Date

Request for Graduate Course Addition - Page 2

College: COHP | Department/Division: Public Health | Alpha Designator/Number: PH 616

Provide complete information regarding the new course addition for each topic listed below. Before routing this form, a complete syllabus also must be attached addressing the items listed on the first page of this form.

1. FACULTY: Identify by name the faculty in your department/division who may teach this course.

William F. Pewen, Ph.D., M.P.H., future faculty, and such as the dean and program director shall designate

2. DUPLICATION: If a question of possible duplication occurs, attach a copy of the correspondence sent to the appropriate department(s) describing the proposal. Enter "***Not Applicable***" if not applicable.

Not applicable

3. REQUIRED COURSE: If this course will be required by another deparment(s), identify it/them by name. Enter "***Not Applicable***" if not applicable.

Not applicable

4. AGREEMENTS: If there are any agreements required to provide clinical experiences, attach the details and the signed agreement. Enter "***Not Applicable***" if not applicable.

Not applicable

5. ADDITIONAL RESOURCE REQUIREMENTS: If your department requires additional faculty, equipment, or specialized materials to teach this course, attach an estimate of the time and money required to secure these items. (Note: Approval of this form does not imply approval for additional resources.) Enter "***Not Applicable***" if not applicable.

College of Health Professions is responsible for hiring faculty. No other resources required at this time.

6. COURSE OBJECTIVES: (May be submitted as a separate document)

See Syllabus

7. COURSE OUTLINE (May be submitted as a separate document)

See Syllabus

8. SAMPLE TEXT(S) WITH AUTHOR(S) AND PUBLICATION DATES (May be submitted as a separate document)

Piantadosi, S. Clinical Trials: A Methodologic Perspective, 2nd Edition. (2005) Wiley-Interscience. ISBN 978-0471727811

Friedman, LM, Furberg, CD, DeMets, DL. Fundamentals of Clinical Trials, 4th edition. (2010) Springer 978-1441915856

Brody, T. Clinical Trials, 1st Edition. (2011) Elsevier ISBN 978-0123919113

9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)

Lecture; course readings; class discussion; research problem set assignments, on-line compliance training module.

10. EXAMPLE EVALUATION METHODS (CHAPTER, MIDTERM, FINAL, PROJECTS, ETC.)

Quizzes
Problem Sets
Completion of On-line Training Module
Final examination

11. ADDITIONAL GRADUATE REQUIREMENTS IF LISTED AS AN UNDERGRADUATE/GRADUATE COURSE

Not applicable

12. PROVIDE COMPLETE BIBLIOGRAPHY (May be submitted as a separate document)

Bonhoeffer, J., Imoukhuede, E. B., Aldrovandi, G., Bachtiar, N. S., Chan, E.-S., Chang, S.. Brighton Collaboration Clinical Trial Protocol Working, G. (2013). Template protocol for clinical trials investigating vaccines--focus on safety elements. Vaccine, 31(47), 5602-5620.

Coakley, M., Fadiran, E. O., Parrish, L. J., Griffith, R. A., Weiss, E., & Carter, C. (2012). Dialogues on Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials. Journal of women's health (2002), 21(7), 713-716.

Dresser, R. (2013). Subversive Subjects: Rule-Breaking and Deception in Clinical Trials. The Journal of Law, Medicine & Ethics, 41(4), 829-840. doi: 10.1111/jlme.12093

Erlen, J. A., Tamres, L. K., Reynolds, N., Golin, C. E., Rosen, M. I., Remien, R. H., . . . Liu, H. (2015). Assessing Usual Care in Clinical Trials. Western Journal of Nursing Research, 37(3), 288-298. doi: 10.1177/0193945914526001

Hao, T., Rusanov, A., Boland, M. R., & Weng, C. (2014). Clustering clinical trials with similar eligibility criteria features. Journal of Biomedical Informatics, 52, 112-120. doi: 10.1016/j.jbi.2014.01.009

Kharrazi, H., Wang, C., & Scharfstein, D. (2014). Prospective EHR-Based Clinical Trials: The Challenge of Missing Data. Journal of General Internal Medicine, 29(7), 976-978. doi: 10.1007/s11606-014-2883-0

Li, J., & Lu, Z. (2012). Systematic identification of pharmacogenomics information from clinical trials. Journal of Biomedical Informatics, 45 (5), 870-878. doi: 10.1016/j.jbi.2012.04.005

Pocock, S. J., & Gersh, B. J. (2014). Do current clinical trials meet society's needs?: a critical review of recent evidence. Journal of the American College of Cardiology, 64(15), 1615.

Ratner, J., Mullins, D., Buesching, D. P., & Cantrell, R. A. (2013). Pragmatic clinical trials: U.S. payers' views on their value. The American Journal of Managed Care, 19(5), e158.

Schapira, L., & Schutt, R. (2011). Training Community Health Workers About Cancer Clinical Trials. Journal of Immigrant and Minority Health, 13(5), 891-898.

Schulz, K., Altman, D., & Moher, D.. (2010) CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ, 340, 698-702.

Vanderpool, R. C., Kornfeld, J., Mills, L., & Byrne, M. M. (2011). Rural–urban differences in discussions of cancer treatment clinical trials. Patient education and counseling, 85(2), e69-e74.

Vawdrey, D. K., & Hripcsak, G. (2013). Publication bias in clinical trials of electronic health records. Journal of Biomedical Informatics, 46(1), 139-141.

Wujcik, D., & Wolff, S. N. (2010). Recruitment of African Americans to National Oncology Clinical Trials through a Clinical Trial Shared Resource. Journal of Health Care for the Poor and Underserved, 21(1A), 38-50.

Request for Graduate Course Addition - Page 5

Please insert in the text box below your course summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department:
Course Number and Title:
Catalog Description:
Prerequisites:
First Term Offered:
Credit Hours:

Department: Public Health
Course Number and Title: PH 616 - Clinical Trials
Catalog Description: An examination of methods and issues in conducting clinical research. Includes critical aspects of study design, protocol development, recruitment and consent, and assessment of outcomes.
Prerequisites: PH 611, PH 621
First Term Offered: Fall 2015
Credit Hours: 3

COURSE TITLE/NUMBER	Clinical Trials PH 616
SEMESTER/YEAR	Fall 2015
DAYS/TIME	Monday 6:00-9:00 p.m.
CREDIT HOURS	3
LOCATION	CHH 1599
INSTRUCTOR	William Pewen, PhD, MPH
OFFICE/PHONE	218 Prichard Hall, 696-3743
E-MAIL	pewen@marshall.edu
OFFICE HOURS	3:00-5:00 pm Wed., 9:00-10:00 am Fri., and by appointment
CFE/UNIVERSITY POLICIES	By enrolling in this course, you agree to the *Marshall University Policies*, and thus it is essential that you understand them. Please review these at the Academic Affairs website: http://muwww-new.marshall.edu/academic-affairs/policies/

COURSE DESCRIPTION: FROM CATALOG

An examination of methods and issues in conducting clinical research. Includes critical aspects of study design, protocol development, recruitment and consent, and assessment of outcomes.

PREREQUISITES:

Successful completion of PH 611 (Epidemiology) and PH 621 (Statistical Methods I), or their equivalents.

STUDENT LEARNING OUTCOMES IDENTIFIED IN THIS COURSE:

Upon completion of the course, students will:

1. Demonstrate understanding of the role of clinical trials in health research, and its appropriate and ethical application.
2. Exhibit knowledge of the design, conduction, analysis and interpretation of clinical trials.
3. Demonstrate knowledge of compliance requirements by completion of on-line training.

COURSE STUDENT LEARNING OUTCOMES	HOW PRACTICED IN THIS COURSE	HOW ASSESSED IN THIS COURSE
Goal 1. Demonstrate understanding of the role of clinical trials in health research, and its appropriate and ethical application.	Readings, lecture, discussion.	Quizzes, Final Examination.
Goal 2. Exhibit knowledge of the design, conduction, analysis and interpretation of clinical trials.	Readings, lecture, discussion, problem-based learning exercises.	Quizzes, Problem Sets, Final examination.
Goal 3. Demonstrate knowledge of compliance requirements by completion of on-line training.	Readings, discussion, assigned on-line training module.	Successful completion of module.

REQUIRED TEXTS, ADDITIONAL READING, AND OTHER MATERIALS

Piantadosi, S. Clinical Trials: A Methodologic Perspective, 2nd Edition. (2005) Wiley-Interscience. ISBN 978-0471727811

RECOMMENDED MATERIALS

Personal computer and smartphone (iPhone or Android) are required.

Additional recommended readings:

- Friedman, LM, Furberg, CD, DeMets, DL. Fundamentals of Clinical Trials, 4th edition. (2010) Springer 978-1441915856
- Brody, T. Clinical Trials, 1st Edition. (2011) Elsevier ISBN 978-0123919113 .

COURSE REQUIREMENTS / DUE DATES

1. Quizzes (Weeks 5, 7, 9, 11, 15)
2. Problem Sets (Weeks 8, 13)
3. On-line Clinical Research Training Module (Week 12)
4. Final Exam (Week 16)

GRADING POLICY

Quizzes (5 given, lowest score dropped)	20%
Problem Sets	30%
Clinical Research Training Module	20%
Final Exam	30%

Grades will be determined by the following scale:

90-100	A
80-89	B
70-79	C
60-69	D
<60	F

ATTENDANCE POLICY

This class meets weekly. While attendance is not required, lectures may not be replicated on Blackboard, and in-class assessments are graded, thus students are encouraged to maintain regular attendance.

ADDITIONAL POLICIES

1. **Accountable material and preparation.** Class sessions are conducted based on the expectation that students complete all appropriate readings and/or assignments as scheduled. This facilitates better questions, discussion, and learning. Exam and quiz questions may be based on both out-of-class assignments and material presented in class.
2. **Electronic devices.** Electronic devices (smartphones, PDAs, laptops, etc.) can be a valuable asset in the classroom. However, if used inappropriately, these can be a distraction. Students should utilize these devices in class only for educational purposes, and are requested to be unobtrusive in their use (including silencing cell phone ringers). Please note that social media, "tweeting", and real time chat are not appropriate in the classroom unless part of a classroom exercise.
3. **Intellectual property notice:** Many materials used in this class are copyrighted, while others represent content and product of the instructor and/or Marshall University. While students may share notes and engage in discussions regarding their work in the course, recording or distribution of course content is not permitted. Students should enquire of the instructor for clarification regarding exceptions.
4. **Academic integrity:** Students should refer to the Student Handbook to ensure understanding of policies concerning academic honesty and integrity, including plagiarism and cheating. Unless specified by the instructor, no electronic devices, notes, or other non-approved assistance is permitted during any exam.
5. **Disability accommodation.** The instructor will endeavor to accommodate students with a disability. It is requested that the student notify the instructor at the earliest possible time regard anticipated assistance which may be required.
6. **Vigilance.** Students are expected to access their MU e-mail address and MU On-line regularly for information related to the course.
7. **Missed classes:** If you are absent, it is the student's responsibility to find out from a classmate what notes, handouts, assignments, or other course material you missed and to make arrangements to receive those.
8. **Make-up assignments and exams:** Students who miss scheduled exams or assignments may make them up in the event of a University-excused absence or medical emergency. In any other situation, a student may request a make-up, but if the request is granted, such may be a different exam or assignment.
9. **Office hours:** As posted and by appointment**.**
10. **Inclement Weather:** If inclement weather results in class cancellation, students are directed to carefully review posted material posted for that session, as we will endeavor to maintain the planned course schedule, including exams which may include that content.

Projected Course Schedule

Week	Date	Topic
1	Aug 24	Applications & Planning
2	Aug 31	Ethical Issues
3	Sep 7	HOLIDAY – Labor Day
4	Sep 14	Populations: External Validity, Power & Sampling
5	Sep 21	Trial Designs
6	Sep 28	Randomization & Blinding
7	Oct 5	Recruitment and Consent
8	Oct 12	Outcomes: Endpoints, Biomarkers & Surrogacy
9	Oct 19	Data Monitoring & Study Termination
10	Oct 26	Analysis and Intent to Treat
11	Nov 2	Clinical Efficacy
12	Nov 9	CONSORT Guidelines
13	Nov 16	Open Topic
14	Nov 23	HOLIDAY - Thanksgiving Break
15	Nov 30	Review
16	Dec 7	Final Exam