

General Information								
Course Title:	Special Topics: Database Management		Course Designation: HES 597B			Credits: 1		
Semester:	Summer		Year:	2008				
Department:	Public Health Sciences							
Co-Directors	Neal Thomas, M.D. M.S. Rosanne Pogash, M.P.A.		Phone #	5337 7689	Email:	nthomas@psu.edu rpogash@psu.edu	Office Rm #	MB H7513 ASB 2404C
Time :	7:30 - 9:55 am		Days:	Fridays (May 23 through June 27)			Location:	C1847B

Course Information

Description and/or Overview:

Covers development and implementation of plans for managing clinical research data, collection and processing data, and ensuring data quality. Students will learn how data management processes fit into the overall research study and how to develop an effective data management plan before a research study begins. The information presented in this course will be helpful to clinical investigators as well as research staff at all levels.

Goals and/or Objectives:

By the end of this course, students will be able to:

- Develop a data management plan that fits the size, scope, and budget of a given research study
- Design data collection forms
- Define variables and coding schemes for data entry
- Choose an electronic system for data capture and storage
- Define rules for identifying problem data
- Understand common sources of introducing data errors into a study and procedures for detecting, correcting, and documenting these errors
- Develop quality assurance procedures to minimize data errors
- Understand how good data management practices fit into the Good Clinical Practice (GCP) guidelines for conducting, recording, and reporting trial data involving human subjects.

The course co-directors will demonstrate the principles of each topic using a mock clinical trial that will be presented to the class during the first session.

Pre-requisites:

None

Requirements; course-specific policies and expectations:

A mock clinical trial will be presented by the course co-directors to the students during the first session. The students will use the mock trial as the basis for completing in-class small group assignments each week. The classes will be structured to include a 1-1.5 hour overview by the course co-directors of the topic for the week followed by a 1 hour small group assignment. Additional time may be required outside of the designated class time to complete the assignment.

All students are expected to:

- Attend each session
- Actively participate in discussions each week
- Share their experiences in conducting clinical research studies with the class
- Actively participate in the in-class assignments

Required Texts and Resources:

The following textbook is not required, but highly recommended: Management of Data in Clinical Trials, Eleanor McFadden, John Wiley & Sons, Inc., New York, 1998. This text contains background information to better understand the topics that will be presented during class. The information presented in class will be distributed to the students during class and will be available on the ANGEL course website.

Electronic Links:

ANGEL will be used to provide online course information. All handouts and other materials will be distributed to students via ANGEL. The site also will contain links to other sites where additional information such as organizations, procedures, and guidelines related to clinical data management can be accessed.

Attendance Policy:

In order to receive a grade of A, a student must attend all six sessions. One failure to meet the attendance requirement will reduce the grade to a maximum of A-, two to a grade of B, and three to a grade of C. More than four breaches in attendance will result in a grade of I or F. It is recognized that legitimate circumstances may on rare occasions prevent attendance at a session; in that case, the student must contact Dr. Neal Thomas or Rosanne Pogash at least one week prior to the expected absence and arrange to satisfy the attendance option. The attendance option will include reading the relevant chapter(s) in the textbook and will include completing an assignment that was included in the small group activity during class.

Examination Policy:

There are no examinations in this course.

Grading Criteria:

The final course grade will be determined by the course co-directors from the following three components (weighted as indicated): class attendance (50%); classroom participation (25%); contribution to small group assignments (25%).

Academic Integrity

Academic Integrity at Penn State is defined by Faculty Senate Policy 49-20 as “the pursuit of scholarly activity in an open, honest and responsible manner”. The University's Code of Conduct states that “all students should act with personal integrity, respect other students' dignity, rights and property, and help create and maintain an environment in which all can succeed through the fruits of their efforts.

Academic integrity includes a commitment not to engage in or tolerate acts of falsification, misrepresentation or deception. Such acts of dishonesty violate the fundamental ethical principles of the University community and compromise the worth of work completed by others”. Academic dishonesty (including, but not limited to cheating, plagiarism, or falsification of information) will not be tolerated and can result in academic or disciplinary sanctions such as a failing (F) grade in the course.

Plagiarism

The students are not required to submit any papers representing original work. Students may refer to external resources in order to complete the in-class assignments.

[For more information, see: <http://tlt.its.psu.edu/suggestions/cyberplag/cyberplagstudent.html>]

Statement on Remediation

The basis for grades, as stated in [Senate Policy 47-20](#), is "...the instructor's judgment of the student's scholastic achievement..." Occasionally, a disagreement arises in the assignment of a grade. A student who wishes to question or challenge the grade assigned in a course must first discuss grading practices and assignments with the instructor. It is expected that the student and instructor will try to eliminate any misunderstandings and will attempt to work out any disagreements over grades.

On the rare occasion that a student and instructor fail to resolve the grade dispute through informal means, the student may request that the head of the academic program offering the course act as a mediator. If this mediation does not resolve the dispute, the student who is a graduate student may request further mediation from the associate dean for graduate studies.

[For more information, see: <http://www.psu.edu/dept/oue/aappm/G-10.html>]

Educator's Code of Conduct

The Penn State Milton S. Hershey Medical Center and Penn State College of Medicine are dedicated to developing and maintaining a strong commitment to ethical teaching practices at all levels of the education process.

The foundation for this Educator's Code of Conduct is provided by the Penn State University Graduate School Statement on Teaching Ethics (1). The development of this Graduate School statement was based on a special issue of the journal, *New Directions for Teaching and Learning*. In this special issue, entitled *Ethical Dimensions of College and University Teaching: Understanding and Honoring the Special Relationship between Teachers and Students* (2), several authors provided theoretical and practical guidelines for honing ethical college teaching skills. Some of the authors' recommendations have been used to formulate the Educator's Code of Conduct provided herein. Some of these recommendations were modified to specifically fit the needs of both educators and students at the Hershey Medical Center and the Penn State College of Medicine. Both the Unified Campus Commitment to Excellence of the Hershey Medical Center and Penn State College of Medicine (3) and the Code of Ethical Behavior of the Hershey Medical Center, Policy A-20 HAM (4) were also consulted in preparing this Educator's Code of Conduct.

Four Norms to Govern Teaching

Honesty

Honesty and integrity must be practiced during all aspects of the education process.

Promise-Keeping

Promise keeping requires the educator to fulfill the "promises" made at the beginning of the semester or any other learning activity. Syllabi, assignments, grading principles, and class and office hour schedules each involve promises that are made to students and that must be adhered to under normal circumstances.

Respect for Persons

The educator must approach the learner with personal respect. In addition, the educator ought to encourage mutual respect among students. In particular, respect for race, religion, sexual orientation, disability gender, age, marital status, cultural differences, and political conviction should be supported and encouraged in all aspects of the educational process. Additionally, educators ought to show respect and common courtesy for students both during interpersonal interactions and in responding promptly to students' need for guidance and feedback. An environment free from harassment and discrimination, verbal abuse, physical violence, and intimidation in any form must also be provided for all learning activities.

Fairness

Recognizing the inherent subjectivity involved in grading, an educator ought to ensure that their grading practices are as objective as possible by creating and adhering to unambiguous criteria.

Principles of Ethical College and University Teaching

Content Competence

An educator maintains a high level of subject matter knowledge and ensures that the content of the educational experience is current, accurate, representative, and appropriate to the position of the learning experience within the students' program of study. The educator must be capable of approaching each learner with a commitment to meeting his or her educational needs.

Pedagogical Competence

A pedagogically competent educator communicates the objectives of the educational experience to students, is aware of alternative instructional methods or strategies, and selects methods of instruction that are effective in helping students to achieve the course objectives.

Dealing with Sensitive Topics

Topics that students are likely to find sensitive or discomfiting are dealt with in an open, honest, and positive way.

Student Development

The overriding responsibility of the educator is to contribute to the intellectual development of the student, at least in the context of the educator's own area of expertise, and to avoid actions such as exploitation and discrimination that detract from student development.

Dual Relationship with Students

To avoid conflict of interest, an educator does not enter into dual-role relationships with students that are likely to detract from student development or lead to actual or perceived favoritism on the part of the educator. The establishment of a romantic/sexual relationship between an educator and a student should be reported to the immediate supervisor of the educator. Such relationships should be dealt with consistent with Penn State Administrative Policy AD41 — Sexual Harassment (5).

Student Confidentiality

Student grades, letters of evaluation, attendance records, and private communications are treated as confidential materials and are released only with student consent, for legitimate academic purposes, or if there are reasonable grounds for believing that releasing such information will be beneficial to the student or will prevent harm to the student or to others.

Patient Privacy and Confidentiality

Educators who utilize patient information as part of any educational experience must follow patient privacy and confidentiality guidelines as outlined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Respect for Colleagues

An educator respects the dignity of his or her colleagues and works cooperatively with colleagues in the interest of fostering student development.

Valid Assessment of Students

An educator is responsible for taking adequate steps to ensure that the assessment of a student's performance is valid, open, fair, and congruent with the course/educational experience objectives. An educator must be aware that such assessments are important in students' lives and in the development of their careers.

Respect for Institution and Profession

In the interest of student development, an educator is aware of and respects the educational goals, policies, and standards of the institution in which he or she teaches and the profession which he or she represents.

Citing Sources of Educational Material

An educator acknowledges and documents, as appropriate, the sources of information and other materials used for teaching.

Violations of the Educator's Code of Conduct

Should a learner experience conduct that is inconsistent with the Educator's Code of Conduct, he/she is encouraged to first address the issue with either the educator responsible for the inconsistency or the director of the course in which the educator teaches. Should this attempt to resolve the problem fail, or if the nature of the inconsistency is such that the learner does not feel comfortable addressing the issue with either the educator or the course director, the student may consult other individuals. These individuals may include but are not limited to: faculty advisor, student ombudsman, departmental chair, the Vice Dean for Educational Affairs, and the Vice Dean for Faculty and Administrative Affairs. The decision of who to contact may be dependent on the educational program of the learner and/or type of violation that was encountered.

References:

- (1) <http://www.gradsch.psu.edu/research/ethics.html#teaching>)
- (2) <http://cte.uncwil.edu/et/br030697.htm>
- (3) Unified Campus Commitment to Excellence of the Penn State Milton S. Hershey Medical Center and College of Medicine; 05/11/01
- (4) Code of Ethical Behavior of the Hershey Medical Center, Policy A-20 HAM; Effective Date October, 2001
- (5) <http://guru.psu.edu/POLICIES/Ad41.html>

Developed by the Unified Campus Academic Team Endorsed by Teams Council — May 21, 2003

Course Schedule

Course Title:		Special Topics: Database Management	Course Designation:	HES 597B	
Course Director:		Neal Thomas, M.D. M.S. and Rosanne Pogash M.P.A.			
Time :	7:30 - 9:55 am		Days:	Friday	Location: C1847B
Date	Lecture #	Instruction Type (Lecture or lab)	Instructor (Last name, First name)		Projected Lecture Topic - This list is an approximate guide to lecture topics. Titles and content are subject to change
05/23/08	1	Lecture	Thomas, Neal and Pogash, Rosanne		Overview of Clinical Data Management Presentation of Clinical Trial
05/30/08	2	Lecture	Thomas, Neal and Pogash, Rosanne		Data Collection Forms Design
06/06/08	3	Lecture	Thomas, Neal and Pogash, Rosanne		Date Files and Database Structures
06/13/08	4	Lecture	Thomas, Neal and Pogash, Rosanne		Data Entry Systems
06/20/08	5	Lecture	Thomas, Neal and Pogash, Rosanne		Data Validation
06/27/08	6	Lecture	Thomas, Neal and Pogash, Rosanne		Quality Assurance Procedures

Contact Information

Faculty / Title	Department	Phone #	EMAIL	Office Room #	Mail Code
Kathy Simon , Adm. Asst.	Graduate Student Affairs	6608	ksimon@psu.edu	1712	H170
Neal Thomas, M.D. MSc Course Co-director	Pediatric Critical Care	5337	nthomas@psu.edu	H7513	H085
Rosanne Pogash, M.P.A. Course Co-director	Public Health Sciences	7689	rpogash@psu.edu	ASB 2404C	A210
Mardi Sawyer Program Administrator	Public Health Sciences	1286	Mds21@psu.edu	2405A	A210