

Medical and Research Ethics
Clinical Elective: ASMD 607-07, 9 Credit Hours
Graduate Course: ASMD 704-01, 3 Credit Hours
Meharry Medical College, January, 2002
Room B-101, West Basic Sciences Building

Course Coordinators: **Carey Szetela, Ph.D.**
Room 247, 2nd Floor, Old Hospital
Mailbox: Pediatrics Office, Old Hospital
327-5909
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Office Hours: by appointment (please call or e-mail to arrange)

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Other Instructors:

Italo Biaggioni, M.D. (Vanderbilt Medical Center)
Peter Dolce, Ph.D. (Meharry Medical College)
David Grandison, M.D., Ph.D. (Meharry Medical College)
George Hill, Ph.D. (Meharry Medical College)
John Lachs, Ph.D. (Vanderbilt University)
Bruce White, D.O., J.D. (Centennial Pediatrics)
And other Guest Lecturers

Description

The focus of this course is applied ethics in clinical and research environments. Course activities include both seminar instruction and clinical experience. Through active engagement with ethical issues in seminars, readings, and clinical settings, students will develop comprehension, applied problem-solving skills, and leadership skills in clinical and research ethics, as well as enhancing their ethical sensitivity to clinical encounters of all kinds.

Seminar Component

Students will meet Mondays, Wednesdays, and Fridays for seminar lectures and discussions. Daily seminars will typically include 3 components:

1. Topical Lecture/Discussion
2. Case Discussion or Student Case Presentation
3. Invited Expert Speaker

Clinical Component

Students will spend Tuesdays and Thursdays each week engaging in clinical and research settings under the direction of a Coordinator and Preceptor. In addition to encountering routine clinical activities that involve ethical dimensions, Preceptors may discuss the ethical dimensions of clinical practices with students, and may offer exposure and readings for students to experience the realities of clinical and research ethics. In addition, students will observe scheduled IRB meeting/s and Ethics Committee meeting/s. Other exposure to ethical decision-making bodies will be offered as opportunities arise. **Students will NOT engage in clinical practice or any "hands-on" patient care.**

Objectives

This course will allow participants to:

1. Recognize, and develop a sensitive awareness to, ethical problems in medicine and medical research.
2. Understand diverse views and how alternative views may each be ethically justifiable based upon different moral frameworks.
3. Apply ethical principles to cases in medicine and research.
4. Understand and apply the principle of informed consent.
5. Understand ethical issues involving special populations in medicine and medical research.
6. Develop skills for research ethics leadership in one's profession and community.

Class Meeting Dates and Locations

With the exception of Friday, January 11, upon which the seminar will convene at St. Thomas Hospital, all lectures will take place in the conference room associated with B101, West Basic Science Building. Students will also be assigned to rotating clinical sites for the Tuesday and Thursday Rotations, as well as to IRB and HEC meeting sites and dates. Clinical sites and coordinators are identified on the Clinical Site and Contact List sheets, to be distributed on Monday, January 9.

Required Texts

Charles Junkerman and David Schiedermayer, **Practical Ethics for Students, Interns and Residents: A Short Reference Manual**. University Publishing Group, 2nd ed. (1998). (To be provided.)

Course Binder including selected readings (to be provided and augmented throughout the course).

Other Course Materials: Students are expected to do independent research, accessing scholarly books, journals, and websites, in support of their case study, Human Subjects Protection Certification Module, and other class assignments.

An ethics library including Books and Journals is available for students in Dr. Szetela's office.

Attendance Policy

School policy requires attendance at a minimum of 80% of scheduled course activities. However, your attendance is expected at 100% of such activities. Participation in classroom discussions and clinical rotations constitute a significant portion of your grade.

Missed classes and rotations, if excused with a notice from the Office of the Associate Dean for Student and Academic Affairs, **MUST** be documented and made up in accordance with instructions from the course coordinator. Unexcused absences may not be made up and your grade will reflect such deficiencies.

Senior medical students will be allowed a maximum of two excused absences (total of two days) to attend residency interviews. Such reasons for absence must be documented (airplane tickets, letter of confirmation from site to be visited, etc.) Other students will be allowed a maximum of two excused absences (total of two days) with documentation and as deemed appropriate by the Course Coordinator.

Examination and Grading Procedures

<i>Attendance</i> and participation in classroom discussions (8%); surprise quizzes (5%)	13%
<i>Clinical Rotations</i>	30%
Preceptor Evaluations	12%
Clinical Rotation Activities and Ethics Log	18%
<i>Human Subjects Protection Certification Module</i> (due Monday, Jan. 14)	10%
<i>Case Presentation</i> (with critical commentary and literature resources)	25%
<i>Final examination</i>	20%
<i>Completion of end-of-course evaluations</i>	2%

No make-up assignments will be permitted without prior permission from Dr. Szetela

A	=	90 - 100
B+	=	85 - 89
B	=	80 - 84
C+	=	75 - 79
C	=	70 - 74
F	=	below 70

Attendance, Participation, and Quizzes: Attendance and promptness are expected of you. Students are expected to complete the readings before coming to class or going to the rotation site. Participation will be counted in your grade, and surprise quizzes will be used to verify your promptness and reading. There will be no make-ups for surprise quizzes, including those completed in the first 5 minutes of a session.

Clinical Rotations: It is a privilege offered our class to attend and observe at a number of clinical sites in Nashville. Students will attend rotation sites, including clinical sites and a variety of ethics oversight committee meetings, alone or in pairs. The schedule for site visits will be distributed for each student on Monday, January 9. Students will need to bring with them contact information for the site coordinator/s, a c.v. or biosketch, confidentiality form/s, the preceptor's evaluation form, their activities and ethics log form, and any other appropriate materials. Grading will be based upon the preceptor's evaluation of the student (total 12%), and the information and ethical reflection demonstrated in the Clinical Rotation Activities and Ethics Log (total 18%). Students will not be evaluated on their rating of the clinical opportunity on the log form, as the purpose of this information is to help us optimize the opportunity for future students.

Professional demeanor is critical to the preceptors' evaluations of the student, and is essential to help foster the professional relationships offered through this course. Please bring promptness, courtesy, and professional appearance to each of your clinical activities. If you must be late for a clinical rotation, you should inform the coordinator or their associate, as well as Dr. Szetela, as soon as you are able.

Respect for the confidentiality of information gained in clinical opportunities is required. A confidentiality agreement must be signed by each student and delivered to each rotation site, and violations of confidentiality will be strictly penalized. Confidentiality will be discussed at the first class,

and any questions about how to ensure confidentiality should be directed to Dr. Szetela or another course faculty member.

Human Subjects Protection Certification Module: (at <http://gra.sdsu.edu/cphs/tutorial/>)

This program was developed by San Diego State University's Committee for the Protection of Human Subjects. It offers an engaging and substantive entry into the basics of the ethics and standards of human subjects research. For general purposes, viewers off-site should substitute the phrase "An IRB" in place of "The CPHS" to represent how human subjects are protected at academic research institutions other than SDSU.

Students must bring their certificate demonstrating completion and passing of the certification assessment (with a 90% score needed to pass) on Monday, January 14.

Case Presentation (30 minutes for presentation and discussion, with critical commentary and literature resources): Students will present a case based on their course-related clinical experiences or prior experiences and interests. The case will include critical commentary on the ethical issue, explain important facets of the issue at hand, and offer an ethical response to the issue, considering the moral weight of opposing viewpoints. A methodology for developing a critical case study will be discussed in class, based upon the ACP model, "A Case Method To Assist Clinical Ethics Decision Making."

Final Exam: The class final will be similar in format to the pre-test, based in part upon USMLE and IRB certification questions.

End-of-Course Evaluations: Students will be required to complete course evaluations of both the classroom and the clinical components.

Stipends

Students participating in the January, 2002, offering of the Medical and Research Ethics elective / course (ASMD 607-07 / ASMD 704-01) may be awarded a stipend of \$750.00.

Receipt of such stipend is dependent upon satisfactory completion of all required coursework. Satisfactory is defined as 1) a grade of A or B, 2) appropriate professional behavior at all rotation sites, and 3) maintenance of patient confidentiality. It is anticipated that stipend checks will be available at or shortly after the completion of the course.

Finally, if you need help, wish to discuss an issue, or if I can assist you in any way, please don't hesitate to reach me.

Clinical Elective in Medical and Research Ethics: Meharry Medical College, January 2002

Thu-3: 9 – 10:20 10:30 – noon 1:00 – 2:30 2:45 – 4:00	C. Szetela, Ph.D.: Organization and Requirements, Pre-Evaluation and Test (Tab 1) J. Lachs, Ph.D.: What is Ethics? (Tab 3) B. White, D.O., J.D.: Clinical Ethics Methodology and Professionalism (Tab 3) K. Dennis, M.D.: Ethics Survival Skills from the Trenches (TBA Tab 4)
Fri-4: 9-10:20 10:30 – noon 1:00 – 2:00 2:00 – 4:00	M. Bliton, Ph.D.: Special Topic in Clinical Ethics: Maternal-Fetal Surgery (TBA Tab 6) C. Szetela, Ph.D.: How to Develop an Ethics Case Study (Tab 3) R. Sneed: Minority Issues in Medical Care (Tab 4) Film: Miss Evers Boys
Mon-7: 9-10:20 10:30 – 11:30 11:30 – noon Noon – 1:00 1:00 – 2:30 2:15 – 3:15 3:15 – 4:00	T. Mether, Ph.D.: Accessing Ethics Resources (TBA Tab 8) C. Szetela, Ph.D.: USMLE Ethics Strategies (TBA Tab 3) C. Szetela, Ph.D.: Clinical Site Placement (TBA Tab 2) Luncheon: Families As Classroom Teachers: Ethical Issues from a Family (Tab 4) Szetela/TBA: Informed Consent (Tab 4) C. Szetela, Ph.D.: Rationing Assignment (Tab 4) Pathogen Video
Wed-9: 9-10:20 10:30 – noon 1:00 – 2:30 2:45 – 3:45	H. Davis, Ph.D.: Spirituality: Addressing Your Patient's Needs (TBA Tab 4) Case Discussions (All) D. Hardison, M.D.: Beginning of Life Issues: OB/GYN, Neonatology (TBA Tab 5) D. Grandison, M.D., Ph.D.: Clinical Research Primer (Tab 6)
Fri-11: 9:00-10:30 10:45 – 12:00 On own: Human Subjects Protection Certification Module (at http://gra.sdsu.edu/cphs/tutorial/)	Activities to be held at St. Thomas Hospital, Conference Room 8 J. Johnson, M.D.: Delivering Bad News (TBA Tab 4) B. White, D.O., J.D.: Informed Consent Exercise (TBA Tab 4)
Mon-14: 9-10:20 10:30 – noon Noon – 1:00 1:00 – 2:30 2:45 – 3:45	<i>Human Subjects Protection Module Certification Due</i> I. Biaggioni, M.D.: History of Research Ethics (TBA Tab 6) <i>Case Discussions</i> Frank, Jason Luncheon: R. Hood, Ph.D.: Confessions of a Research Subject (Tab 5) K. Payne, R.N., J.D.: End-of-Life Decision Making (TBA Tab 5) C. Szetela, Ph.D.: Ethics Committee Primer (Tab 7)
Wed-16: 9-10:20 10:30 – noon 1:00 – 2:30 2:45 – 4:00	D. Brown, Ph.D.: Challenges for Physicians and Patients in Rural Settings (TBA Tab 4) <i>Case Discussions</i> Karen, Clarence P. Dolce, Ph.D.: IRB Primer (Tab 6) M. Hubbard: The Patient's Perspective (TBA Tab 4)
Fri-18: 9 – noon noon –	L. Sander, Ph.D./G. Hill, Ph.D.: RCR, Animal Use, Mock IACUC (TBA Tab 6) Independent Study
Wed-23: 9-10:20 10:30 – noon 1:00 – 2:30 2:45 – 3:45	TBA: Case Discussion – Debriefing (All) G. Shu Tangyie, M.D.: The Challenge of Doctoring from the Heart (TBA Tab 4) Genetics Video
Fri-25: 9 – 9:45 9:45 – 11:15 11:30 – 12:30	<i>Post-Evaluation</i> J. Lachs, Ph.D.: The Moral Life (Tab 3) <i>Test</i>

Meharry Medical College, Medical Ethics Student Schedule, January 2002 REVISED

Questions: Contact Dr. Szetela at 327-5909 or 385-4171 (home), or Dr. Mether at 327-5914

Student 1

T 8: Alive Hospice
Th 10: MNGH Social Services
T 15: St. Thomas Transplant
Th 17: VUMC Geriatrics
F 18: GCTC Research
T 22: MNGH NICU
HEC: Centennial Medical Center, T 8
IRB: VUMC, Th 10 (bring specialized confidentiality form)
Case Study Presentation: M 14

Student 2

T 8: Alive Hospice
T 15: MNGH NICU
Th 17: VUMC Geriatrics
F 18/S 19: GCTC Research
T 22: St. Thomas Transplant
Th 24: MNGH Social Services (or follow up with Dr. Szetela to replace with Dialysis or Pediatrics)
HEC: Make-up MNGH Feb. 11
IRB: MMC, T 22 (bring specialized confidentiality form)
Case Study Presentation: W 16

Student 3

T 8: St. Thomas Transplant
Th 10: VUMC ASAP Research, VUMC GIG
T 15: MNGH NICU
Th 17: Alive Hospice
T 22: VUMC Geriatrics
Th 24: MNGH Social Services
HEC: VUMC, T 15
IRB: VUMC, Th 17
Case Study Presentation: M 14

Student 4

T 8: St. Thomas Transplant
Th 10: MNGH ICU (If no ICU schedule conflict, do Geriatrics Make-up at VUMC 7th Flr, MCE, 1:30 – 2:30)
T 15: Absent: Geriatrics Make-up TBA _____
Th 17: Alive Hospice
T 22: VUMC NICU
Th 24: VUMC CTC Research, VUMC GIG
HEC: Make-up MNGH Feb. 11
IRB: VUMC, Th 17
Case Study Presentation TBA _____

Student 5

T 8: MNGH NICU
Th 10: VUMC Geriatrics
T 15: St. Thomas Heart Transplant
Th 17: MNGH Social Services
T 22: Alive Hospice
Th 24: VUMC CTC Research, VUMC GIG
HEC: MNGH, M 14
IRB: St. Thomas, M 7
Case Study Presentation: W 16

Clinical Elective in Medical and Research Ethics: Meharry Medical College, January 2002 Clinical Sites and Contacts:

Meetings

IRB (Institutional Review Board)

MMC: Dr. Frank Hatcher
T 22; 3pm.
Basic Sciences Building, Room ____

VUMC: Dr. Jim Atkinson, 343-9576/322-3058, Robin Ginn 343-4093/322-2257/835-7809
Th 10, 17, 24; 11 – 1:00 (lunch provided)
Room ____

St. Thomas: Dr. Bart Campbell, Martha Green (IRB Coordinator), Melinda Turner (Liason, 322-3677)
M 7 (and possibly M 21); 7am
Administrative Conference Rooms

HEC (Hospital Ethics Committee)

MNGH: Adrienne Black,(COO), Robbie Newlin (Admin. Assistant)
M 14, 9:30am
MNGH 11th Floor Boardroom

VUMC: Dr. Stuart Finder (936-2686)
T 15; 4pm
Room ____

St. Thomas: Dr. John Johnson, Kate Payne (222-6449)
W 2, 7am
Admin Conference Rooms (take seats around wall)

Centennial Medical Center: Dr. James Sullivan
T 8, 7am
Meet in advance at physicians' lounge, 3rd Floor of Medical Center (have breakfast)

VUMC GIG and Public Health Seminar (Genetics Interest Group and Public Health Ethics Class): Dr. John Phillips, Dr. Carol Freund (322-6767)
Th 10/24: Noon – 2pm
Light Hall, Room 412

MMC CRC Lunch Series: Dr. Joseph Hinds
F 18, 12 – 1:30

Clinical Sites

Alive Hospice: Dr. John Mulder (963-4830), Virginia Harris (Mulder's assistant, 327-1085), Ossie Corlie (Team Leader, Charge Nurse), Jeff (963-4764)
7am Morning Report and 3:00 for shift change; Team Meetings Tuesday (for home care) Thursday 9:30 (for residents)
Arrive at 6:55
1710 Patterson St. (*at Charlotte and 17th)
Parking in lot no charge
Read Tab 5, *State Initiatives in End-of-Life Care* (Missouri)
*30 beds, keeping relatively full; end-of-life decisions

MNGH NICU: Karen Cummins-Marks (MNGH Neonatal Nurse Practitioner, 341-4240), Dr. Samuel Ishmael (Director), Dr. Bobbie Byrne (Physician Coordinator, T/Th 8/10), Dr. Sarah Hassell (Physician Coordinator, T/Th 15/17 or 22/24), Dr. Susan Campbell (Physician Coordinator, T/Th 15/17 or 22/24), Beckie Bond (Liason, 342-4660)

4th Floor

Read Tab 5, *The Baby Doe Cases*

*issues in critical care for neonates, parental concerns

VUMC Geriatrics: Dr. James Powers (936-3274), (and Dr. Ralph Haberman (?))

Team Meetings, Tuesdays 8:30 – 9:30 (Vanderbilt) and 9:30 – noon (V.A.); Thursdays 1:30 – 2:30

Tuesdays, Arrive 8:15am at 7th Floor, VUMC Medical Center East, Depart from V.A. Hospital TBA (probably noon)

Thursdays, Arrive 9:55 at Ward 2G, VA Hospital; and Arrive VUMC Medical Center East 1:15, Depart 2:30

Dress professionally (men should wear tie)

MNGH ICU: Dr. Darryl Jordan (327-5896/6373), ICU 341-4325

3rd Floor

*issues in critical care

MNGH Social Services: Sandra McMahan (see tab 2 for Social Services contact information list)

Arrive 9am

2nd Floor (in wing perpendicular to escalators)

*discharge planning, patient advocacy, social issues

Research Sites

VUMC CTC (Clinical Trials Center): Lynda Lane (936-1737)

Arrive 7:45am, Depart TBA (probably lunchtime)

1500 21st Ave. South, Suite 3500 Village at Vanderbilt

Parking: Free temporary parking is available in the surface lot on site. On-site garage parking is available at \$3.50/2 hrs.

* research subjects awaiting liver transplants

VUMC ASAP (Asthma, Sinus, and Allergy Program): Dr. John Murray, Brendie Kean (936-5764)

Arrive 7:30am, Depart 10:30-11:00

2611 West End Ave., Suite 210

Vanderbilt GCRC (General Clinical Research Center, Vanderbilt + Meharry): Dr. Mac Buchowski (342-2603, 322-9442, PG: 835-4992 (best to leave number, not voice))

Vanderbilt GCRC, 3rd Flr MCN (wing alongside 21st Ave.)

Park in Medical Center lot and bring stub for validation

Friday 2-5:30pm: admissions process + 2 tests

Saturday 6am-noon: metabolic room + exercises

(Patient leaves Sunday 1pm)

*Pediatrics Sickie-Cell Protocol: Read Informed Consent document

MMC CRC (Clinical Research Center): Dr. John Grandison, Levenia Crutcher (Program Coordinator)

St. Thomas Transplantation: Kate Payne (Medical Ethicist, 222-6449)

T 8/15/22 Meetings 7am

Arrive 6:45am, Depart TBA

Administrative Conference Rooms

Read Tab 4, Cohen et. al., *Alcoholics and Liver Transplantation*

*Heart Transplant Meetings followed by clinical observation and discussions