RECEIVED

APR 1 2013

OFFICE OF THE SENATE COUNCIL

1. General Information

1a. Submitted by the College of: MEDICINE

Date Submitted: 4/1/2013

1b. Department/Division: Behavioral Science

1c. Contact Person

Name: William W. Stoops

Email: william.stoops@uky.edu

Phone: 859-257-5383

Responsible Faculty ID (if different from Contact)

Name:

Email:

Phone:

1d. Requested Effective Date: Specific Term/Year [1] Fall 2013

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?: No

2b. Prefix and Number: BSC 534

2c. Full Title: Ethics and Responsibility in Clinical Research

2d. Transcript Title: Clincal Research Ethics

2e. Cross-listing:

2f. Meeting Patterns

SEMINAR: 2

OTHER: 1

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?

2j. Course Description for Bulletin: Clinical scientists need a sound understanding of the ethical principles guiding the conduct of research projects. This course will address issues relevant to ethically sound study design, responsible conduct of research and scientific misconduct. Students will also complete human subjects protection training and learn to conduct research in an ethical manner. During this course, students will engage in both in-class lecture and discussion sessions as well as out of class learning activities (outlined below). The final project for graduate students for this course will serve as a practical application of what is learned during the course to students' stated research interest. The goal of this course is to provide an overview of ethical considerations when conducting and reporting clinical research, as well as to provide experience in the practice and application of ethics to clinical science. It is assumed by the course directors that students in this course are either actively engaged in clinical research or intend to be involved in clinical research in the near future. This course has been designed around the principle that practical knowledge about how to conduct ethical research should be the focus. A second key principle of this course is that it is student-centered, meaning that it emphasizes the involvement of students in applying the concepts of ethics to their own research interests. The course activities are intended to promote the ethical application of research concepts to students' areas of interest and to foster practical knowledge that supports students' own research agendas. The diverse interests and experiences of students and faculty offer opportunities to learn from each other.

2k. Prerequisites, if any: This course is designed for scholars pursuing research training in clinical and translational science to integrate and apply knowledge obtained in previous training. Permission is required from the Course Director for entry into the class.

2l. Supplementary Teaching Component:

3. Will this course taught off campus? No

   If YES, enter the off campus address:

4. Frequency of Course Offering: Fall,

   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?: 8-12

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?: Yes

   If Yes, explain: [var7InterestExplain]

8. Check the category most applicable to this course: Not Yet Found in Many (or Any) Other Universities ,

   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?: Yes

If YES, list affected programs: If the course is approved, it will become an option for meeting the ethics and responsible conduct of research training in the Certificates in Clinical and Translational Science and Clinical Research Skills.

10. Information to be Placed on Syllabus.

a. Is the course 400G or 500?: Yes

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:

Instructor Email:

Internet/Web-based: No

Interactive Video: No

Hybrid: No

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?

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.

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.

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?

If yes, which percentage, and which program(s)?

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?

6.How do course requirements ensure that students make appropriate use of learning resources?

7.Please explain specifically how access is provided to laboratories, facilities, and equipment appropriate to the course or program.

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/)?

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.

10.Does the syllabus contain all the required components? NO

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

Instructor Name:

SIGNATURE|CLEUKEF|Carl G Leukefeld|Dept approval for ZCOURSE_NEW BSC 534|20120820

SIGNATURE|LDEARING|Lana S Dearinger|College approval for ZCOURSE_NEW BSC 534|20120821

SIGNATURE|JDLIND2|Jim D Lindsay|HCCC approval for ZCOURSE_NEW BSC 534|20121029

SIGNATURE|JMETT2|Joanie Ett-Mims|Undergrad Council approval for ZCOURSE_NEW BSC 534|20121129

SIGNATURE|ZNNIKO0|Roshan N Nikou|Graduate Council approval for ZCOURSE_NEW BSC 534|20130204

e

Courses	Request Tracking

New Course Form

https://myuk.uky.edu/sap/bc/soap/rfc?services=

Open in full window to print or save

Generate F

Attachments:

Browse... Upload File

	ID	Attachment
Delete	1286	BSC 534 syllabus.doc

First 1 Last

Select saved project to retrieve... Get New

(*denotes required fields)

1. General Information

a. * Submitted by the College of: MEDICINE Today's Date: 4/1/2013

b. * Department/Division: Behavioral Science

c.
* Contact Person Name: William W. Stoops Email: william.stoops@uky.edu Phone: 859-257-5383
* Responsible Faculty ID (if different from Contact) Email: Phone:

d. * Requested Effective Date: ○ Semester following approval OR ◉ Specific Term/Year [1] Fall 2013

e.
Should this course be a UK Core Course? ○ Yes ◉ No
If YES, check the areas that apply:

☐ Inquiry - Arts & Creativity	☐ Composition & Communications - II
☐ Inquiry - Humanities	☐ Quantitative Foundations
☐ Inquiry - Nat/Math/Phys Sci	☐ Statistical Inferential Reasoning
☐ Inquiry - Social Sciences	☐ U.S. Citizenship, Community, Diversity
☐ Composition & Communications - I	☐ Global Dynamics

2. Designation and Description of Proposed Course.

a. * Will this course also be offered through Distance Learning? ○ Yes [4] ◉ No

b. * Prefix and Number: BSC 534

c. * Full Title: Ethics and Responsibility in Clinical Research

d. Transcript Title (if full title is more than 40 characters): Clincal Research Ethics

e. To be Cross-Listed [2] with (Prefix and Number):

f. * Courses must be described by at least one of the meeting patterns below. Include number of actual contact hours[3] for each meeting pattern type.

	Lecture		Laboratory[1]		Recitation		Discussion
	Indep. Study		Clinical		Colloquium		Practicum
	Research		Residency	2	Seminar		Studio
1	Other	If Other, Please explain:		Out of class learning activities (e.g., human subjects training, bioethic			

g. * Identify a grading system: ◉ Letter (A, B, C, etc.) ○ Pass/Fail

h. * Number of credits: 3

i. * Is this course repeatable for additional credit? ○ Yes ◉ No
If YES: Maximum number of credit hours:
If YES: Will this course allow multiple registrations during the same semester? ○ Yes ○ No

j. * Course Description for Bulletin:

Clinical scientists need a sound understanding of the ethical principles guiding the conduct of research projects. This course will address issues relevant to ethically sound study design, responsible conduct of research and scientific misconduct. Students will also complete human subjects protection training and learn to conduct research in an ethical manner. During this course, students will engage in both in-class lecture and discussion sessions as well as out of class learning activities (outlined below). The final project for graduate students for this course will serve as a practical application of what is learned during the course to students' stated research interest. The goal of this course is to provide an overview of ethical considerations when conducting and reporting clinical research, as well as to provide experience in the practice and application of ethics to clinical science.
It is assumed by the course directors that students in this course are either actively engaged in clinical

k. Prerequisites, if any:

This course is designed for scholars pursuing research training in clinical and translational science to integrate and apply knowledge obtained in previous training. Permission is required from the Course Director for entry into the class.

l. Supplementary teaching component, if any: ○ Community-Based Experience ○ Service Learning ○ Both

3. * **Will this course be taught off campus?** ○ Yes ◉ No

If YES, enter the off campus address:

4. **Frequency of Course Offering.**

a. * Course will be offered (check all that apply): ☑ Fall ☐ Spring ☐ Summer ☐ Winter

b. * Will the course be offered every year? ◉ Yes ○ No

If No, explain:

5. * **Are facilities and personnel necessary for the proposed new course available?** ◉ Yes ○ No

If No, explain:

6. * **What enrollment (per section per semester) may reasonably be expected?** 8-12

7. **Anticipated Student Demand.**

a. * Will this course serve students primarily within the degree program? ◉ Yes ○ No

b. * Will it be of interest to a significant number of students outside the degree pgm? ◉ Yes ○ No

If YES, explain:

Students requiring clinical ethics training will likely seek to take the course as such classes are limited on campus.

8. * **Check the category most applicable to this course:**

☐ Traditional – Offered in Corresponding Departments at Universities Elsewhere
☐ Relatively New – Now Being Widely Established
☑ Not Yet Found in Many (or Any) Other Universities

9. **Course Relationship to Program(s).**

a. * Is this course part of a proposed new program? ○ Yes ◉ No

If YES, name the proposed new program:

b. * Will this course be a new requirement [5] for ANY program? ◉ Yes ○ No

If YES [5], list affected programs::

If the course is approved, it will become an option for meeting the ethics and responsible conduct of research training in the Certificates in Clinical and Translational Science and Clinical Research Skills.

10. **Information to be Placed on Syllabus.**

a. * Is the course 400G or 500? ◉ Yes ○ No
If YES, the *differentiation for undergraduate and graduate students must be included* in the information required in 10.b. You must include: (i) ident additional assignments by the graduate students; and/or (ii) establishment of different grading criteria in the course for graduate students. (See SR

b. ☑ * The syllabus, including course description, student learning outcomes, and grading policies (and 400G-/500-level grading differentiation if appl 10.a above) are attached.

☐ Courses are typically made effective for the semester following approval. No course will be made effective until all approvals are received.
☑ The chair of the cross-listing department must sign off on the Signature Routing Log
☑ 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. Laboratory meeting, generally, re two hours per week for a semester for one credit hour. (Form SR 5.2.1)
☑ You must also submit the Distance Learning Form in order for the proposed course to be considered for DL delivery.
☑ In order to change a program, a program change form must also be submitted.

Rev 8/09

Submit as New Proposal Save Current Changes Delete Form Data and Attachments

BSC 534: Ethics and Responsibility in Clinical Research
Tuesdays, 5:00-7:30 PM, Room TBD

Course Director
William W. Stoops, Ph.D.

Email
william.stoops@uky.edu

Office Address
465 East High Street, Suite 204B, Lexington, KY 40507

Office Phone
859-257-5383

Office Hours
By appointment

Course Description

Clinical scientists need a sound understanding of the ethical principles guiding the conduct of research projects. This course will address issues relevant to ethically sound study design, responsible conduct of research and scientific misconduct. Students will also complete human subjects protection training and learn to conduct research in an ethical manner. During this course, students will engage in both in-class lecture and discussion sessions as well as out of class learning activities (outlined below). The final project for this course for graduate students will serve as a practical application of what is learned during the course to students' stated research interest. The goal of this course is to provide an overview of ethical considerations when conducting and reporting clinical research, as well as to provide experience in the practice and application of ethics to clinical science.

It is assumed by the course director that students in this course are either actively engaged in clinical research or intend to be involved in clinical research in the near future. This course has been designed around the principle that practical knowledge about how to conduct ethical research should be the focus. A second key principle of this course is that it is *student-centered*, meaning that it emphasizes the involvement of students in applying the concepts of ethics to their own research interests. The course activities are intended to promote the ethical application of research concepts to students' areas of interest and to foster practical knowledge that supports students' own research agendas. The diverse interests and experiences of students and faculty offer opportunities to learn from each other.

Course Objectives

In this course, all students will:

1. Gain an understanding of key issues in the conduct of ethical clinical research.

2. Learn current human subjects protection standards.

3. Develop an appreciation for the gravity of research misconduct and how to handle suspected or documented misconduct.

In addition, graduate-level students will:

4. Design and prepare an Institutional Review Board research protocol application in their area of interest.

5. Participate in a mock Institutional Review Board meeting during which each student's research protocol application will be reviewed by the group for ethical strengths and concerns.

Learning Outcomes

After completing this course, students will be able to:

1) Describe human subjects protection standards.

2) Analyze the contribution of past human subjects research abuses and scientific misconduct to current ethical research practices.

3) Distinguish between appropriate scientific behavior and scientific misconduct, in addition to developing ways to avoid and rectify scientific misconduct.

4) Integrate content from topic issues and prepare thought papers relating these topics to their research interests.

In addition, graduate-level students will:

4. Prepare Institutional Review Board research protocol applications.

5. Formulate critiques of Institutional Review Board research protocol applications.

Prerequisites

This course is designed for scholars pursuing research training in clinical and translational science to integrate and apply knowledge obtained in previous training. Permission is required from the Course Director for entry into the class.

Course Materials

Course materials include book chapters, journal articles and portfolio activities. You may wish to purchase one text: *Ethical and Regulatory Aspects of Clinical Research* (edited by Ezekiel J. Emanuel, Robert A. Crouch, John D. Arras, Jonathan D. Moreno and Christine Grady, 2003) as this will serve as the "core" text for the course. This book is available from online sellers, such as Amazon (http://www.amazon.com) or Barnes & Noble (http://www.bn.com). Journal articles can be downloaded via UK's Electronic Journals website (http://sfx.uky.edu:3210/sfxlcl3/azlist/default) or are available in the class Dropbox Readings subfolder. Students should have received an invitation to join Dropbox and share the course folder/subfolders prior to the first class. Anyone not having access to the folder should email Dr. Stoops. Case studies from *On Being a Scientist* are also available in the Dropbox Readings subfolder.

Course Activities and Expectations

Learning will be facilitated through a combination of assigned readings, written activities and group discussions in the classroom. These activities include:

1) Core readings that provide an overview of the ethical issues under discussion for each in-class meeting. It is expected that students will have completed the readings before class meets.

2) Thought papers will be completed by undergraduate students each week that there is content discussion and each week that the course does not have a scheduled, in-class meeting. Graduate students will complete thought papers each week that the course does not have a scheduled, in-class meeting. These are due to the course director by 12 PM on each date noted in the syllabus below. Papers should be brief (1-2 pages) and should consider how the topic for the week (e.g., Vulnerable Populations) or out of class activity (e.g., online experience, manuscript or chapter reading) applies to each student's area of research.

3) In-class lecture and discussions of important concepts related to research ethics, how students might apply research ethics to their own interests and key "lessons learned" from research experiences, such as how decisions about conducting ethical research were made and how ethical challenges during the research process were addressed. For each in-class meeting, generally no more than thirty minutes will be lecture-based, which will essentially highlight the assigned readings. The remaining time will be spent discussing the topics and assigned readings. For each topic, there will be two "local experts" who, with the course director, will be responsible for guiding and stimulating class discussion. The two local experts for each topic will present a case study from *On Being a Scientist*, which may or may not be directly applicable to that day's topic. The local experts will be responsible for outlining the relevant facts of the case, discussing the ethical principles at stake, providing a resolution for the case and recommending ways to avoid similar issues in the future. Each case also has a series of thought questions that should be posed to the whole class. This course is intended to

be an interactive experience for both students and the course director, so participation in discussions is expected.

4) Core materials for an Institutional Review Board protocol application (according to University of Kentucky Medical IRB Standards) and Presentation for a research project in each student's area of interest. This requirement is for graduate-level students only.

5) An ethical review board experience after completion of the IRB application. This activity will provide students with feedback about the ethical issues involved in their research project while also giving them the experience of preparing constructive feedback for other students in the course. This feedback will be given during a mock meeting in which each protocol prepared by students will be discussed by the group—special attention should be paid to ethical strengths and concerns in these protocols. This requirement is for graduate-level students only, although all students are expected to attend this class meeting.

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 director's 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 director. Unexcused absences will result in the forfeiting of the points for those class meetings. Late submissions of written activities will result in a 10% point penalty per day.

Maximum point values for course activities for undergraduate-level students are as follows:

Attendance and participation during class meetings: 10 class meetings @ 10 points each = 100 possible points
"Local Expert" Assignments: 60 points
Thought Papers: 9 thought papers @ 10 points each = 90 possible points

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

A: 225 – 250 points
B: 200 – 224 points
C: 175 – 199 points
D: 150 – 174 points
E: 149 points or less

Maximum point values for course activities for graduate-level students are as follows:

Attendance and participation during class meetings: 10 class meetings @ 10 points each = 100 possible points
"Local Expert" Assignments: 60 points
Thought Papers: 2 thought papers @ 10 points each = 20 possible points
IRB Protocol Application and Presentation: 70 points (50 points for application, 20 points for presentation)
Peer Review Activity: 50 points for completing written review of assigned IRB application (20 points) and participating in mock ethical review board meeting (30 points)

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

A: 270-300 points
B: 240-269 points
C: 210 – 239 points
E: 209 points or less

Detailed Outline of Topics, Readings, and Activities for the Course

WEEK 1: August 27, 2013

Class meets for Topic 1, "Introduction to the Course"
During this meeting we will also discuss each student's primary research interest/area of specialty and sign up for "local expert" topics.

WEEK 2: September 3, 2013

Class does not meet this week. Assigned activity: Complete Human Subjects Protection Training (or if you are already trained, complete Refresher Course). This training is available at http://www.citiprogram.org/. Upon completion, write a thought paper about how this training applies to your area of research.

WEEK 3: September 10, 2013

Class meets for Topic 2, "Introduction to Ethics and Ethical Research"
From *Ethical and Regulatory Aspects of Clinical Research*:

1) Scandals and Tragedies of Research with Human Participants: Nuremburg, the Jewish Chronic Disease Hospital, Beecher and Tuskegee. Pages 1-5.
2) Ethics and Clinical Research. Pages 16-20.
3) The Nuremburg Code. Page 29.
4) The Declaration of Helsinki. Pages 30-32.
5) The Belmont Report. Pages 33-38.

6) The Common Rule. Pages 39-55.

Other Articles:

1) Cave, E. & Holm, S. (2003). Milgram and Tuskegee—Paradigm Research Projects in Bioethics. *Health Care Analysis, 11,* 27-40.
2) Krugman, S. (1986). The Willowbrook hepatitis studies revisited: Ethical aspects. *Reviews of Infectious Diseases, 8,* 157-162
3) Rothman, D.J. (1982). Were Tuskegee and Willowbrook "Studies in Nature"? *Hastings Center Report, 12,* 5-7.

Case Study: Discovering an Error.

Undergraduate Students: Write a thought paper about how this topic to your area of research interest.

WEEK 4: September 17, 2013

Class meets for Topic 3, "Use of Humans in Research"

From *Ethical and Regulatory Aspects of Clinical Research*:

1) The Ethics of Research Participant Recruitment. Pages 151-154.
2) Philosophical Reflections on Experimenting with Human Subjects. Pages 155-161.

Other Articles:

1) Cody, R. (2006). Anticipating risk for human subjects participating in clinical research: Application of failure mode and effect analysis. *Cancer Investigation, 24,* 209-214.
2) Phillips, T.B. (2011). A Living Wage for Research Subjects. *The Journal of Law and Medical Ethics, 39,* 243-253.
3) Wong, J.C. & Bernstein M (2011). Payment of Research Subjects for More than Minimal Risk Trials is Unethical. *The American Journal of Medical Sciences, 342,* 294-296.

Case Study: Tests on Students.

Undergraduate Students: Write a thought paper about how this topic to your area of research interest.

WEEK 5: September 24, 2013

Class meets for Topic 4, "Vulnerable Populations"

From *Ethical and Regulatory Aspects of Clinical Research*:

1) Wanted: Single, White Male for Medical Research. Pages 166-171.
2) Why Should We Include Women and Minorities in Randomized Controlled Trials. Pages 171-175.
3) The Duty to Exclude. Pages 175-178.
4) Research Involving Persons with Mental Disorders that May Affect Decision Making Capacity. Pages 229-233.
5) Convenient and Captive Populations. Pages 258-262.

Other Articles:

1) Hayes, M.O. (2006). Prisoners and autonomy: Implications for the informed consent process with vulnerable populations. *Journal of Forensic Nursing,* 2, 84-89.
2) Sayre, S. (February 17, 2010). France: Report says army troops exposed to radiation. *New York Times.*
3) Belluck, P. (February 15, 2010). Wanted: Volunteers, all pregnant. *New York Times.*

Case Study: A Career in the Balance.

Undergraduate Students: Write a thought paper about how this topic to your area of research interest.

WEEK 6: October 1, 2013

Class meets for Topic 5, "Informed Consent"

From *Ethical and Regulatory Aspects of Clinical Research*:

1) Informed Consent in Research. Pages 189-195.
2) Consent Issues in Human Research. Pages 197-201.
3) Informed (But Uneducated) Consent. Pages 202-203.
4) A Moral Theory of Informed Consent. Pages 203-207.
5) Is Informed Consent Always Necessary for Randomized, Controlled Trials? Pages 207-210.

Other Articles:

1) Festinger, D.S., Marlowe, D.B., Croft, J.R., Dugosh, K.L., Arabia, P.L., & Benasutti, K.M. (2009). Monetary Incentives Improve Recall of Research Consent Information: It Pays to Remember. *Experimental and Clinical Psychopharmacology, 17*, 99-104.

Case Study: A Change of Plans.

Undergraduate Students: Write a thought paper about how this topic to your area of research interest.

WEEK 7: October 8, 2013

Class meets for Topic 6, "IRB Applications"

Review the information and links on the following web pages:

1) IRB Review Types. http://www.research.uky.edu/ori/human/IRBReviewTypes.htm
2) Forms and Applications. http://www.research.uky.edu/ori/human/HumanResearchForms.htm
3) IRB Survival Handbook (A to Z). http://www.research.uky.edu/ori/IRB-Survival-Handbook.html

Case Study: Fabrication in a Grant Proposal.

Undergraduate Students: Write a thought paper about how this topic to your area

of research interest.

WEEK 8: October 15, 2013

Class meets for Topic 7, "Research Misconduct"
From *Ethical and Regulatory Aspects of Clinical Research*:

1) Scientific Misconduct. Pages 385-392.
2) Pressure to Publish and Fraud in Science. Pages 393-395.
3) Science, Statistics, and Deception. Pages 395-396.
4) Preventing Scientific Misconduct. Pages 399-402.
5) Underreporting Research is Scientific Misconduct. Pages 411-414.

Other Articles:

1) Editorial (September 10, 2011). An Array of Errors. *The Economist.*
2) Potti, A., Mukherjee, S., Petersen, R., et al., (2006). A Genomic Strategy to Refine Prognosis in Early-Stage Non-Small-Cell Lung Cancer. *New England Journal of Medicine, 355,* 570-580. Retracted in *New England Journal of Medicine* in 2011, *364,* 1176.
3) John, L.K., Loewenstein, G., & Prelec, D. (2013). Measuring the Prevalence of Questionable Research Practices with Incentives for Truth Telling. *Psychological Science, 23,* 524-532.

Case Study: Publication Practices.

Undergraduate Students: Write a thought paper about how this topic to your area of research interest.

WEEK 9: October 22, 2013

Class does not meet this week. Assigned activity (complete one of two options):

1) Read one of the following chapters from the book Research Ethics edited by Ana Smith Iltis. These chapters review research issues and copies are available in Dropbox. After reading the chapter, complete a thought paper about what you learned.
a) Ethical Issues in the Conduct of Genetic Research By Lisa S. Parker and Lauren Matukaitis Broyles.
b) Embryonic Stem Cell Research and Human Therapeutic Cloning: Maintaining the Ethical Tension Between Respect and Research By Gerard Magill.
c) Biomedical Research in the Developing World: Ethical Issues and Dilemmas by David B. Resnik.

2) Attend a Research Ethics Lecture at the University of Kentucky (schedule can be found here: http://ukhealthcare.uky.edu/about/bioethics/Research-Ethics-Lecture-Series.aspx#.UAb1OHArOHk) and prepare a thought paper about what you learned.

WEEK 10: October 29, 2011

Class meets for Topic 8, "Use of Animals in Research" Guest Lecturer: TBD
Articles: To Be Determined. Readings will be provided to you no later than October 22, 2013.
Case Study: A Change of Protocol.

Undergraduate Students: Write a thought paper about how this topic to your area of research interest.

WEEK 11: November 5, 2013

Class does not meet this week. Assigned activity: Submit your IRB Application to course director, who will then distribute applications to your assigned reviewers. Each student will have two specific applications assigned for written review. These two reviews are due Week 14 and will be discussed during the mock IRB meeting in Week 15.

WEEK 12: November 12, 2013

Class meets for students to present their research proposals. These should be 7 minute, power point presentations of the highlights of the proposals and germane ethical considerations, with an additional 3 minutes for questions.

WEEK 13: November 19, 2013

Class does not meet this week due to the Thanksgiving Holiday.

WEEK 14: November 26, 2013

Class does not meet this week. Assigned activity: Prepare written reviews of your assigned IRB application, paying specific attention to ethical research issues, and submit to course director.

WEEK 15: December 3, 2013

Class meets for the mock IRB meeting reviewing IRB Applications. Complete course evaluations.

Course Policies

Submission of Assignments
Assignments are expected by 12 PM (noon) on the days they are due. They should be emailed to the course director.

Attendance Policy
Attendance is expected at each class meeting. Contact Dr. Stoops to request an excused absence.

Excused Absences
Students need to notify Dr. Stoops of absences prior to class when possible. S.R. 5.2.4.2 defines the following as acceptable reasons for excused absences: (a) serious illness, (b) illness or death of family member, (c) University-related trips, (d) major religious holidays, and (e) other circumstances found to fit "reasonable cause for nonattendance" by the professor.

Students anticipating an absence for a major religious holiday are responsible for notifying the instructor in writing of anticipated absences due to their observance of such holidays no later than the last day in the semester to add a class. Information regarding dates of major religious holidays may be obtained through the religious liaison, Mr. Jake Karnes (859-257-2754).

Students are expected to withdraw from the class if more than 20% of the classes scheduled for the semester are missed (excused or unexcused) per university policy.

Verification of Absences
Students may be asked to verify their absences in order for them to be considered excused. Senate Rule 5.2.4.2 states that faculty have the right to request "appropriate verification" when students claim an excused absence because of illness or death in the family. Appropriate notification of absences due to university-related trips is required prior to the absence.

Plagiarism and Cheating
PLAGIARISM and CHEATING are serious academic offenses. The minimum penalty for those academic offenses is final grade E in the assignment.

The University regulations pertaining to this matter can be found at http://www.uky.edu/StudentAffairs/Code/. Of particular relevance is Part II, SELECTED RULES OF THE UNIVERSITY SENATE GOVERNING ACADEMIC RELATIONSHIPS, Section 6.3 that can be found at http://www.uky.edu/StudentAffairs/Code/part2.html.

These rules in particular say: PLAGIARISM All academic work, written or otherwise, submitted by students to their instructors or other academic supervisors, is expected to be the result of their own thought, research, or self-expression. In cases where students feel unsure about a question of plagiarism involving their work, they are obliged to

consult their instructors on the matter before submission.

When students submit work purporting to be their own, but which in any way borrows ideas, organization, wording or anything else from another source without appropriate acknowledgment of the fact, the students are guilty of plagiarism.

Plagiarism includes reproducing someone else's work, whether it be published article, chapter of a book, a paper from a friend or some file, or whatever. 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.

6.3.2 CHEATING Cheating is defined by its general usage. It includes, but is not limited to, the wrongfully giving, taking, or presenting any information or material by a student with the intent of aiding himself/herself or another on any academic work which is considered in any way in the determination of the final grade. Any question of definition shall be referred to the University Appeals Board.

Bad Weather Policy
Any decisions regarding the cancellation of classes, delayed opening or early cancellation of classes due to bad weather will be made by the University's Vice President for University Relations. Up-to-date information in made available through several sources which you may access directly: 1) the UK INFOLINE at 257-5684, 2) UK TV (check your local tv guide for channel number) or WUKY-FM at 91.3 or 3) UK Home Page at www.uky.edu

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.

Policy on Academic Accommodations Due to Disability
If you have a documented disability that requires academic accommodations, please arrange an appointment with a course director as soon as possible. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (Room 2, Alumni Gym, 257-2754, email address

jkarnes@email.uky.edu) for coordination of campus disability services available to students with disabilities.