

Instructor : **Professor Thaddeus Pope**
Course Title : **Bioethics & Law**
Section : **Law 9558, Section 1**
Format : **Take Home**
Total Time for Exam : **48 hours**
Total Number of Pages : **12 Pages**

Reference Materials Allowed

Open Book (all reference materials allowed)

Take-Home Exam Instructions

1. Please know your **correct Spring 2013 exam number** and include this number at the top of each page of your exam answer (for example, in a header). To locate your exam number, go to www.hamline.edu and follow the steps below. A graphic guide to locating your exam number is attached to these instructions.

Click on Logins in the header.
Go to Piperline
Log in to the secure area
Enter your Student ID and PIN
Click Student Services
Click Registration
Click Student Detail Schedule
Select the appropriate term from the drop down menu
Exam Numbers are listed below Total Credit Hours at the top of the page
2. Confirm that you are using and have typed the **correct exam number** on your exam document.
3. You may download the exam from the course TWEN site any time after 4:00 p.m. on Sunday, February 24, 2013. All exams must be submitted within 48 hours of download. But, in any case, all exams must be submitted by the end of the midterm exam period, i.e. by 11:00 p.m. on Saturday, March 2, 2013. Therefore, you will want to download your exam no later than 11:00 p.m. on Thursday, February 28, 2013, to ensure that you have the full allowed 48 hours to complete your exam.
4. Write your answers to BOTH parts of the exam in a word processor. Save your document as a **single PDF file** before uploading to TWEN. Use your exam number as the name for the PDF file.

Instructions Specific to This Examination**GENERAL INSTRUCTIONS:**

1. **Honor Code:** While you are taking this exam, you are subject to the Hamline University Code of Conduct. You may not discuss it with anyone until after the end of the entire exam period. It is a violation of the Honor Code to share the exam questions. Shred or delete the exam questions immediately upon completion of the exam. They will be reposted after the end of the exam period.
2. **Competence:** Accepting this examination is a certification that you are capable of completing the examination. Once you have accepted the examination, you will be held responsible for completing the examination.

3. **Exam Packet:** This exam consists of **12 pages**, including this cover page but excluding the appendix of graphics on getting an exam number and submitting on TWEN. Please make sure that your exam is complete.
4. **Identification:** Write your exam number on the top of each page of your exam answer.
5. **Anonymity:** The exams are graded anonymously. Do not put your name or anything else that may identify you (except for your exam number) on the exam. **Failure to include your correct exam number will result in a 10-point deduction.**
6. **Total Time:** Your completed exam is due within 48 hours of downloading it. If your exam is uploaded more than 48 hours after downloading the exam, your exam grade will be **lowered by one point** for every minute in excess of the 48 hours. If the timestamp on your uploaded exam indicates that you have exceeded the 48-hour limit by more than 15 minutes, the situation may be referred for a Code of Conduct investigation and potential discipline. Please save sufficient time to successfully upload your exam.
7. **Timing:** The exam has been written as a two-hour exam. A student could write basically complete answers to all the questions in two hours. But since this is a take-home exam, you will want to take some extra time (perhaps two hours) to outline your answers and consult your course materials. You will also want to take some extra time (perhaps two hours) to revise and polish your answers, such that you will not be submitting a “first draft.” In short, while this is a 48-hour take home, you really need not spend more than four hours on this exam.
8. **Scoring:** There are 75 total points on the exam. The final exam comprises 25% of your overall course grade, 75 of the 300 total course points.
9. **Open Book:** This is an OPEN book exam. You may use any written materials, including, but not limited to: any required and recommended materials, any handouts from class, PowerPoint slides, class notes, and your own personal or group outlines.
10. **Additional Research:** While you may use any materials that you have collected for this class, you are neither expected **nor are you permitted** to do any online or library research (e.g. on Lexis, Westlaw, Google, Bing, reference materials) to answer the exam questions.
11. **Format:** The exam consists of two parts:
 - PART ONE comprises 30 multiple choice questions worth 1 point each, for a combined total of 30 points.
 - PART TWO comprises three short essay questions worth a combined total of 45 points.
12. **Grading:** All exams will receive a raw score from zero to 75. The raw score is meaningful only relative to the raw score of other students in the class. Your semester course letter grade is computed by summing the midterm, final, and quiz scores. I will post an explanatory memo and a model answer to TWEN a few weeks after the exam.

SPECIAL INSTRUCTIONS FOR PART ONE:

1. **Numbered List of Letters:** In your exam document create a vertical numbered list (1 to 30). Next to each number type the letter corresponding to the best answer choice for that problem.
2. **Ambiguity:** If (and only if) you believe the question is ambiguous, such that there is not one obviously best answer, neatly explain why immediately after your answer choice. Your objection must (i) identify the ambiguity or problem in the question and (ii) reveal what your answer would be for all possible resolutions of the ambiguity. I do **not** expect this to be necessary.

SPECIAL INSTRUCTIONS FOR PART TWO:

1. **Submission:** In your exam document create clearly marked separate sections for each of the three problems:
Short Answer 1
Short Answer 2
Short Answer 3
2. **Outlining Your Answer:** I strongly encourage you to use at least one-fourth of the allotted time per question to outline your answers on scrap paper before beginning to write. Do this because you will be graded not only on the substance of your answer but also on its clarity and conciseness. In other words, organization, precision, and brevity count. If you run out of insightful things to say about the issues raised by the exam question, stop writing until you think of something. Tedious repetition, regurgitations of law unrelated to the facts, or rambling about irrelevant issues will negatively affect your grade.
3. **Answer Format:** This is important. Use headings and subheadings. Use short single-idea paragraphs (leaving a blank line between paragraphs). Do not completely fill the page with text. Leave white space both between sections and paragraphs.
4. **Answer Content:** Address all relevant issues that arise from and are implicated by the fact pattern and that are responsive to the "call" of the question. Do not just summarize all the facts or all the legal principles relevant to an issue. Instead, apply the law you see relevant to the facts you see relevant. Take the issues that you identify and organize them into a coherent structure. Then, within that structure, examine issues and argue for a conclusion.
5. **Citing Cases:** You are welcome but not required to cite cases. While it is sometimes helpful to the reader and a way to economize on words, do not cite case names as a complete substitute for legal analysis. For example, do not write: "Plaintiff should be able to recover under A v. B." Why? What is the rule in that case? What are the facts in the instant case that satisfy that rule?
6. **Cross-Referencing:** You may reference your own previous analysis (e.g. B's claim against C is identical to A's claim against C, because ___." But be very clear and precise what you are referencing. As in contract interpretation, ambiguity is construed against the drafter.
7. **Balanced Argument:** Facts rarely perfectly fit rules of law. So, recognize the key weaknesses in your position and make the argument on the other side.
8. **Additional Facts:** If you think that an exam question fairly raises an issue but cannot be answered without additional facts, state clearly those facts (reasonably implied by, suggested by, or at least consistent with, the fact pattern) that you believe to be necessary to answer the question. Do not invent facts out of whole cloth.

Exam Misconduct

The Code of Conduct prohibits dishonest acts in an examination setting. Unless specifically permitted by the exam or proctor, prohibited conduct includes:

- Discussing the exam with another student
- Giving, receiving, or soliciting aid
- Referencing unauthorized materials
- Reading the questions before the examination starts
- Exceeding the examination time limit
- Ignoring proctor instructions

Multiple Choice Questions

- 30 Questions worth 1 point each = 30 total points.
- Mark the letter of the best answer in a vertical list in your exam document.

- 1. The history of ethical regulations governing research on human subjects research began with the:**
 - A. Nuremburg Code
 - B. Declaration of Helsinki
 - C. Common Rule
 - D. Belmont Report

- 2. Greg is working on his dissertation. Greg plans to interview principals in neighboring high schools. Greg plans to collect data about the personal experiences that the principals have had with disruptive students and what types of disciplinary actions they took. Identifiers will be collected. This study would be categorized as:**
 - A. Expedited Review
 - B. Exempt Review
 - C. Full Board Review
 - D. Not Human Subjects

- 3. Kerry is working on his dissertation. He plans to conduct research on the types of junk food available to the public. Kerry plans to go to the local convenience stores like CVS and ask the managers what types of junk food they normally stock and what are their biggest sellers. Identifiers will not be collected. This study would be categorized as:**
 - A. Expedited Review
 - B. Exempt Review
 - C. Full Board Review
 - D. Not Human Subjects Research

- 4. Which type of IRB review does not require an IRB "approval" but still requires a determination by the IRB or a designee of the IRB?**
 - A. Full Board Review
 - B. Expedited Review
 - C. Exempt
 - D. All of the above
 - E. None of the above

5. Christy plans to track the restrictions that U.S. immigration laws imposed on certain ethnic groups. She plans to do this by reviewing passenger lists from ships that transported immigrants to America between 1840 and 1860. This study would be categorized as:
- Expedited Review
 - Exempt Review
 - Full Board Review
 - Not Human Subjects Research
6. When can research with children be “exempt”?
- When children are 12 years old or older
 - It can never be exempt.
 - When parents request an exemption
 - When it falls into an eligible category of research activity
7. An investigator proposes a study to determine the clinical relevance of a therapy for teenaged (age 13 to 17) patients undergoing chemotherapy. The study requires that three additional bone marrow samples be taken during the course of chemotherapy. The subject's chemotherapy will not be altered based on the results of the measures. However, future patients with cancer would benefit from improved interventions based on the study's findings. The IRB has determined that the study entails a minor increase over minimal risk. Which of the following statements best describes the IRB approval requirements for involving children in the study?
- Assent is not required, but one parent must give permission
 - Assent is not required, but both parents must give permission
 - Both assent of the child and permission of both parents are required
 - Only assent of the child is required

USE THIS FACT PATTERN FOR BOTH QUESTIONS 8 AND 9

Alice is planning federally funded research study involving children who are 7 to 11 years old. Alice's research involves collecting two urine samples from healthy children to measure amounts of protein. Alice's IRB has determined that assent of children age 9 and older is required for the study. One 11-year-old refuses assent to participate in the study described above.

8. Which of the following procedures best describes the required action?
- Consent one of the child's parents instead
 - Request the child to reconsider assenting to the study
 - Honor the child's decision
 - Consent both of the child's parents instead

9. Under the Common Rule, the IRB's risk assessment for this study is probably:
- A. More than minimal risk with prospect of direct benefit to the child
 - B. No more than minimal risk to the child
 - C. More than minimal risk with no prospect of direct benefit to the child
 - D. No risk to the child and no further IRB review is required

USE THIS FACT PATTERN FOR BOTH QUESTIONS 10 AND 11

A Full IRB Committee meeting is convened on February 22, 2013. The IRB Committee roster consists of 17 members. However, only 9 members are in attendance at today's meeting. One of the protocols to be reviewed at this meeting is new research proposing to evaluate how mothers interact with their learning disabled children.

10. Which of the following IRB members must be present during the IRB's discussion and vote on this proposal?
- A. The Principal Investigator for the research proposal under deliberation
 - B. A member who is unaffiliated with the institution
 - C. The non-scientist member
 - D. A social worker
11. The protocol requires that the children in the study be at least six years old. The protocol requires the mother of the child (a) to look at the child without any expression and (b) not to talk to the child for four minutes. One of the IRB members, Frank, is Principal Investigator for the study and receives a portion of his salary from the supporting grant. Frank, the principal investigator, must recuse himself from the IRB room during both the final deliberations and the vote on the study. Which of the following best describes the IRB's action after Frank leaves?
- A. Trust that the study is ethical because Frank is a member of the Committee. Continue with the final deliberations and vote.
 - B. Use an expert in child development as a consulting reviewer to help answer questions in Frank's absence
 - C. Defer the proposal to the next meeting because there is no quorum
 - D. Continue with review, discussion and vote because the minutes will note that Frank abstained from the vote
12. A researcher began a records-based research project. But this researcher later determined that the individuals whose data is being collected must be contacted, to get updated health information. This will require a change to the protocol. What level of IRB review is most likely?
- A. None
 - B. Expedited Review
 - C. Review for Exemption
 - D. Full Board Review

13. **The death of Ellen Roche exposed the following problems with research at Johns Hopkins?**
- A. There were not sufficient IRB resources relative to the number of research protocols
 - B. Failure to respond adequately to a previous adverse event
 - C. Both A and B
 - D. Neither A nor B
14. **Under the Common Rule, "private" information:**
- A. Includes information about behavior, but not existing records
 - B. Includes information about behavior and existing records
 - C. Excludes any behaviors that can be observed
 - D. Can be identified in accordance with universal standards
15. **Brendan is a researcher who wants to investigate regional birth rates. He plans to review public birth records that are available at county court-houses.**
- A. This is human subject research
 - B. This is NOT human subject research
16. **Kelly is a cognitive psychologist. He proposes to recruit undergraduate students for a computer-based study about the effect of mood states on problem-solving performance.**
- A. This is human subject research
 - B. This is NOT human subject research
17. **Milo is a developmental psychologist. He proposes videotaping interactions between pre-school children and their caregivers in a laboratory setting to determine what methods of communication most effectively manage aggression.**
- A. This is human subject research
 - B. This is NOT human subject research
18. **When reviewing federally supported research involving prisoners, an IRB must include the following member(s), in addition to the standard requirements for IRBs, to ensure that the prisoners' perspective is represented:**
- A. Two members who are currently prison guards, wardens or parole officers
 - B. Two members who are employed by the penal system
 - C. One member who is a prisoner or prisoner representative
 - D. One member who is a health care provider at the local hospital where prisoners may be treated

- 19. Jordan has prepared a federally supported research protocol. Her goal is to examine the characteristics and effectiveness of “house arrest,” a program where individuals are confined to their homes under continuous surveillance (e.g. with an electronic ankle bracelet). Which of the following best describes the IRB’s duties when reviewing this research?**
- A. Even though this research involves individual subjects who would be considered prisoners and examines an alternative to incarceration, the IRB does not have any additional duties
 - B. Since this research involves individual subjects who would be considered prisoners and examines an alternative to incarceration, the IRB should ensure that the additional requirements for prisoner research are met
 - C. Since this research is federally supported, the IRB does not have any duty to review this research
 - D. Since this research does not involve individual subjects who would be considered prisoners, the IRB does not have any additional duties
- 20. Which of the following studies meets the definition of “research” with human subjects?**
- A. A study in four 3rd grade classrooms about the relationship between the time of day reading is taught and improved reading comprehension.
 - B. The collection of data about the physical dimensions of public school playgrounds by a contracted playground designer
 - C. An analysis of Minnesota Department of Education aggregate data comparing statewide public high school graduation rates
 - D. None of the above
- 21. The Nuremberg Code:**
- A. Had an immediate and profound influence on how research was conducted in the United States
 - B. Resulted in the establishment of the OHRP
 - C. Was not considered relevant to research practices in the United States
- 22. As defined in the Belmont Report, the ethical principle of respect for person relates to the general rule:**
- A. Obtain consent from subjects
 - B. Maximize possible benefits and minimize potential risks
 - C. The burdens of research should be shared equally
 - D. Children should not be enrolled in research

23. Which of the following is NOT required on an informed consent form?
- A. A contact person for questions about the research
 - B. The purpose of the research
 - C. A description of benefits that may be reasonably expected from the research
 - D. A statement that participation is voluntary
 - E. A list of all personnel who will be involved in the research
24. Derek wants to compare the effect of print media versus electronic social media on individuals' opinions on several social issues. Derek's girlfriend is the warden of a local work release facility. She will allow Derek access to the prison population to help her recruit subjects. Derek will also recruit subjects on his college campus. The study takes just 20 minutes. The risks appear to be no more than minimal. The IRB would most likely:
- A. Approve this project, because the warden is the ultimate authority on what happens in her facility
 - B. Not approve this project because the prisoners are merely a population of convenience
 - C. Approve this project, because the risk is minimal
 - D. Approve this project
25. Which of the following statements about prison research is true?
- A. Participation in research can be considered during parole hearings
 - B. Researchers may study the effects of privilege awards if they are granted by the prison
 - C. The risks involved in the research may be higher than the risks that would be accepted by non-prisoners
 - D. Researchers cannot pay prisoners
26. An investigator is recording non-identifiable information from state records to study the frequency of "handedness" (left hand versus right hand) in a given population. What level of review is most appropriate?
- A. Expedited review by a designated IRB member
 - B. None
 - C. Review by a convened quorum of the IRB
 - D. Determination of exemption
27. In 1966, Henry K. Beecher published an article in the *New England Journal of Medicine* that:
- A. Cites 22 examples of unethical research
 - B. States that the data acquired from unethical research should not be published
 - C. Both A and B
 - D. Neither A nor B

28. Rachael is studying the effects of divorce on children. She proposes to interview children, age 8 to 15, and their parents. Which of the following statements best describes the consent requirements for this study?
- A. The assent process for the children should vary depending upon their age and maturity
 - B. Parental permission is sufficient to enter these child into the study
 - C. If a teacher thinks it would be helpful for a child to talk about divorce, the child may be enrolled without parental permission
 - D. Consent must be obtained and documented for all participants using the same IRB consent form
29. The Belmont Report describes three basic principles relevant to research on human subjects. Those three principles are:
- A. Respect for persons, informed consent, and IRB review
 - B. Justice, beneficence, and special considerations for vulnerable populations
 - C. Respect for persons, beneficence, and IRB review
 - D. Respect for persons, beneficence, and justice
 - E. Beneficence, justice, and IRB review
30. Which are the following are examples of research on human subjects?
- A. Studies that collect data through drug clinical trials on individuals
 - B. Studies that collect data through internet surveys about alcohol consumption
 - C. Studies using private information that can be linked to individuals, even if the information was not collected specifically for the research in question
 - D. A and B
 - E. All of the above

Short Essay Questions

- There are three short essay questions, worth a combined total of 45 points.

Short Essay Question 1

- 10 points
- Limit your answer to 500 words.

An oncologist is treating a patient with colon cancer. Customary chemotherapy drugs have proven ineffective. The oncologist offers her patient the option of trying ABC drugs. ABC drugs are currently used for other types of cancer. They are still being tested for colon cancer, but that research is not yet complete. Although the oncologist is not participating in any of the protocols that concern ABC drugs, she has reviewed preliminary unpublished reports and has had informal discussions with researchers testing ABC drugs. The oncologist has concluded that ABC drugs show promise.

If the doctor gives his patient ABC drugs, is it research?

Short Essay Question 2

- 20 points
- Limit your answer to 750 words.

A nurse anesthetist observes that it is often difficult to intubate seriously overweight adult patients. Because this nurse previously worked at a children's hospital, she suggested that physicians use a pediatric tube for a particular patient in an urgent situation. This was done with great success. Assume that the physicians in the hospital subsequently decides to adopt this "pediatric tube" approach as regular practice whenever they fail a first attempt at intubation in seriously overweight adult patients.

Is this research? What if the nurse presents the "pediatric tube" approach at a nursing "in-service training" at the hospital? What if the nurse makes some alterations to the pediatric tube and decides to seek a patent and license the design to a manufacturer?

Short Essay Question 3

- 15 points
- Limit your answer to 500 words.

YooCare is a private HMO that wishes to research the effects of "withholds" on the behavior of its primary care physicians. Each of the PCPs works exclusively for YooCare. They serve only patients who are members of its HMO. Each YooCare PCP is paid a monthly fee of \$35 per patient on that PCP's list (a capitation model of reimbursement). The YooCare administration wants to involve 25 PCPs in the "withholds" study. They want to randomize half of the patients on each of those physicians' lists to "withhold" status and maintain the other half on "pure" capitation status.

6. Click “Registration.”

The screenshot shows the Hamline University website's main menu. The 'Student Services' tab is active. Below the menu, there is an information icon and a message: 'Access to Financial Aid information has moved. A new menu has been created to access your Financial Aid information. To access, go to the main menu and select "Financial Aid Services" or select the "Financial Aid Services" tab from above.' Below this, several service categories are listed: 'Course/Instructor Evaluations', 'Admissions', 'Registration', 'Student Records', 'Career Services', and 'Additional Student Services'. The 'Registration' link is highlighted with a red box and a red arrow pointing to it from the left.

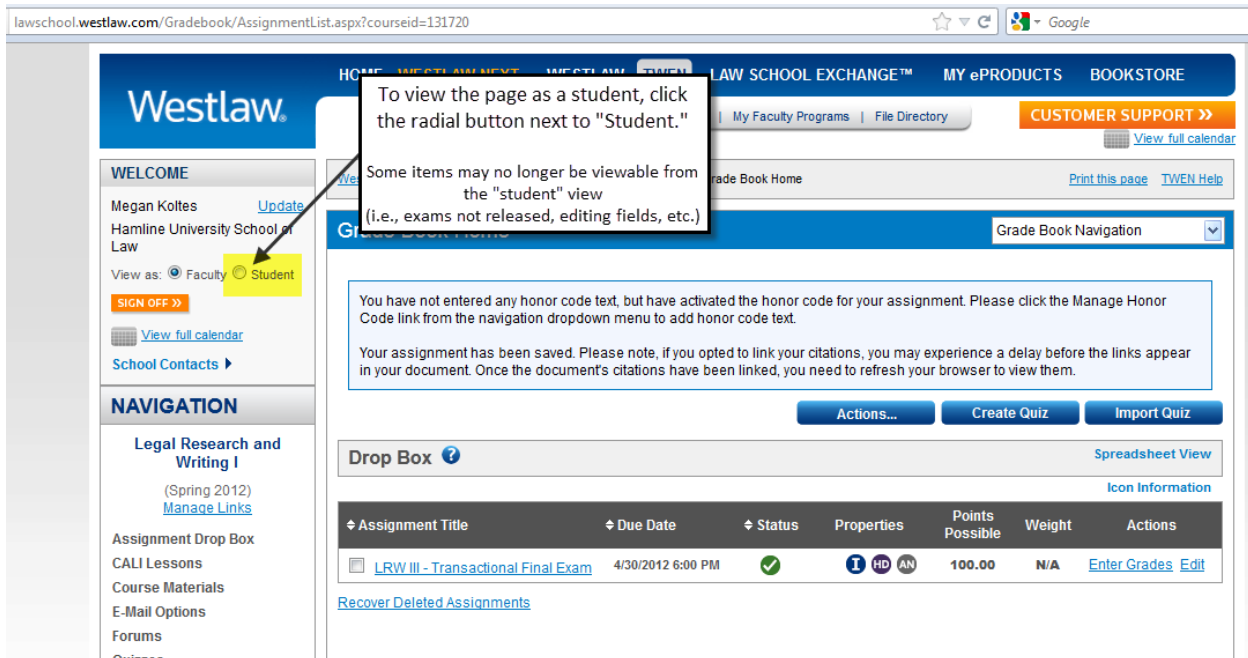
7. Click “Student Detail Schedule.”

The screenshot shows the Hamline University website's 'Registration' page. The 'Registration' tab is active in the main menu. Below the menu, there is an information icon and a message: 'Access to Financial Aid information has moved. A new menu has been created to access your Financial Aid information. To access, go to the main menu and select "Financial Aid Services" or select the "Financial Aid Services" tab from above.' Below this, several service categories are listed: 'Select Term', 'Register/Add/Drop Classes', 'Look-up Classes to Add', 'Student Schedule by Day & Time', 'Student Detail Schedule', 'Check Your Registration Status', and 'Get Your Books'. The 'Student Detail Schedule' link is highlighted with a red box and a red arrow pointing to it from the left.

8. You will then need to select the appropriate term from a drop-down menu (Fall 2011).

TWEN – View as a Student

1. Log on to Westlaw as normal (www.lawschool.westlaw.com).
2. Select the TWEN tab.
3. Under your log-in information in the upper left corner, select the option to view as a student.



The screenshot shows the Westlaw website interface. In the top left corner, under the 'WELCOME' section, there is a 'View as:' dropdown menu with 'Faculty' selected and 'Student' highlighted. A tooltip points to the 'Student' option, stating: 'To view the page as a student, click the radial button next to "Student." Some items may no longer be viewable from the "student" view (i.e., exams not released, editing fields, etc.)'. Below the dropdown, there are buttons for 'SIGN OFF >>', 'View full calendar', and 'School Contacts >'. The main content area shows a message about honor code text and a table titled 'Drop Box' with columns for Assignment Title, Due Date, Status, Properties, Points Possible, Weight, and Actions. The table contains one entry: 'LRW III - Transactional Final Exam' with a due date of 4/30/2012 6:00 PM and a status of 'Completed' (indicated by a green checkmark).

Assignment Title	Due Date	Status	Properties	Points Possible	Weight	Actions
<input type="checkbox"/> LRW III - Transactional Final Exam	4/30/2012 6:00 PM	✓	I HD AN	100.00	N/A	Enter Grades Edit

4. Once an exam has hit the time and date on which it should become available, students will then be able to see it in the "Assignment Drop Box."

