BioE 100 Mid Term Exam
October 19, 2007

+30

ETHICAL CONCEPTS: TRUE OR FALSE (30 POINTS)

305/315 = 97%

1. T. Copyright and patents are ways of protecting ideas from being plagiarized.
2. F. The Belmont Report codifies research ethics on animal experimentation.
3. T. The ordering of importance of primae facie duties depends on the situation.
4. T. A stakeholder includes a company's competitors.
5. T. Telling a lie might be driven by beneficence, but is unethical according to Kantian duty.
6. F. Animal Rights comes to a moral conclusion that animal research is never ethical.
7. T. The development of the respirator helped ignite the Right to Die ethical controversy
8. T. Advanced medical directives grant specific end of life decisions including right to die.
9. F. An ethical argument can be derived from factual premises alone.
10. F. Research misconduct includes honest error or differences of interpretation of valid data
11. F. Listing an author not involved in the research because they are famous is ethically permissible.
12. T. Slippery slope theory argues that a reasonable act might lead to a bad consequence.
13. T. "Begging the Question" assumes that a critical point in a debate is "obviously" true when in fact it needs to be justified or reasoned.
14. F. Ad Hominem is permissible during debate because it supports the moral argument.
15. F. Utilitarian arguments are a defense for science and engineering research misconduct

ETHICAL THEORIES: MULTIPLE CHOICE (60 POINTS) +60

16. Which ethicist asserts "Ethics is not a matter of consequence but of duty."

(a) Jeremy Bentham

(b) Immanuel Kant

(c) Peter Singer

(d) None of the above

17. Utilitarianism is the ethical theory that the morally right course of action in any situation is

(a) one of legal rules, backed by force of opinion and law, which is in everyone's self interest.

(b) to always treat other humans as "end in themselves" and not as "mere means"

(c) to always consider all the stakeholders

(d) the one that produces the greatest balance of benefits over harm for everyone affected

18. To not cause reckless or careless harm

(a) non-malfeasance

(b) justice

(c) autonomy

(d) rights

19. Justice dictates

(a) the need for equal burden and equal benefits

(b) duty to keep commitments

(c) that ethics is a decision about consequences

(d) none of the above

20. Ethical dilemma between the private interests and the official responsibilities of a person in a position of trust

(a) Slippery slope

(b) Research misconduct

(c) Conflict of interest

(d) all of the above

21. Where non-comparable harms are involved, avoid harming the worse-off individual.

(a) the Miniride Principle

(b) the Worse-off Principle

(c) primae facie duty

(d) double effect

22. Virtue ethics involves

(a) courage

(b) wisdom

(c) loyalty

(d) all of the above

23. Moral calculus based on "desire", "preferences", "intention", "understanding."

(a) preference utilitarianism

(b) hedonistic utilitarianism

(c) rights ethics

(d) none of the above

24. Duty is

(a) a binding obligation out of respect for moral law

(b) to increase the general happiness

(c) to treat others as a means to an end

(d) none of the above

25. Autonomy is a central concept to what ethical theory

(a) Rule ethics

(b) Rights ethics

(c) Virtue ethics

(d) none of the above

26. Moral calculus based on happiness and physical pain

(a) preference utilitarianism

(b) hedonistic utilitarianism

(c) rights ethics

(d) none of the above

27. Rights ethics is best associated with which historical issue

(a) Olympic competition

(b) Declaration of Independence

(c) Galileo excommunication for asserting a sun-centric galaxy

(d) none of the above

ETHICAL FRAMEWORKS: SHORT ANSWER OF NO MORE THAN 50 WORDS (75 POINTS)

75

26. Name the 4A's and give 1-2 sentence definition for each component

Aquire Facts - obtain all facts relevant to case + clarify ambiguities

Alternatives - propose Alternative actions, all possible ones, and the stakeholders involved in each one

Assesment - Assess each alternative in the context of the moral theories that apply to them and how each alternative either benefits or harms the Stakeholders involved. (use facts to support as well)

Action - Decide a course of action based on the above to solve the situation keeping in mind to be flexible and adapt if necessary.

27. Define one important ethical theory and why it applies to euthanasia for (a) competent and (b) incompetent patients?

Duty to do the right thing (Kantianism) applies to Euthanasia. For both competent + incompetent patients the doctors and medical staff have a duty to save and preserve life. For competent patients, Autonomy comes into play and the "right thing to do" would be to honor that. But that goes against the doctors duty. For incompetent patients without advanced directives, the duty of the doctor still applies but their Autonomy still needs to be respected through testimonies from close friends + family.

28. Define "company credo" and explain its ethical importance

A company credo is a statement of a companies stakeholders and how they address them. It sets up an ethical guidline for day-to day business and management in terms of a crisis. It should address, the stockholders, consumers(health of), employees, bovernment, Other businesses (competitors, supliers, distributors), the environment, and the public community. So if a crisis happens, the credo will lay out an outline to fix the situation accounting for all stakeholders.

ETHICAL CASE STUDIES: (150 POINTS)

29. Animal Experimentation. Researchers are studying a rare genetic disorder known as osteogenesis imperfecta (OI) that results in brittle bones. Neonates with this disorder usually have many broken bones at birth, and often brain damage, other organ damage, and a variety of infections. Thus they usually die within 6 months to one year. Researchers plan to develop a transgenic mouse with a genetic defect that results in a condition somewhat similar to human OI, and will refine the study later by using 24 dogs (plus 6 without the disease who serve as controls) that suffer from a condition very similar to human OI. They will refine therapeutic protocols first on 100's of transgeneic mice, and then develop more accurate therapeutics using further refinement and testing on the dogs.

Explain if, and why or why not, the proposed study meets each of the guidelines of the following 5R's

Name	Explanation
Replacement:	This is partialy satisfied with the mice. they seem to be the lowest "morally worth" species with bones to conduct the study. the use of dogs is questionable because why can't they get the results they need with only mice. If they must use a higher order animal, they should not use dogs. maybe pigs that are lower than dogs.
Reduction:	This is not satisfied with both the mice and dogs. 100's of mice is too much. They should only use the number of mice that will yield statistically relevant data. maybe 100 or less. 30 dogs is also excesive. If they must use dogs use maybe 5-10 with 2-3 controls. they need to minimize the ~~suffering of~~ total # of suffering animals.
Refinement:	This is partialy satisfied because they are starting out w/mice, refining protocols, then going to the dogs instead of starting out with the dogs. At this stage, they need to do all they can to minimize how much the animals suffer by adjusting the experiment in any way. It is still questionable b/c they are using dogs when they could possibly refine by using a lower morally worth species
Relevance:	This is satisfied. The research is meant to possibly save the lives of Neonate babies that die very young from brain damage, infections, etc. the mice will provide a condition similar to the babies where researchers can learn a lot from. then it will be created in dogs (or another animal) that will be very similar to humans to narrow the treatments.
Redundancy:	This is satisfied also since this research has not been done before.

140

dog OI ~ human OI

#dogs < #mice

30. Human Experimentation. Researchers at the Kennedy Krieger Institute are recruiting healthy children and their parents totaling 108 families to relocate to East Baltimore homes with varying amounts of lead paint contamination to conduct a research study. The purpose of the study is to determine how well different levels of repair in Baltimore rental housing in poor areas works to reduce lead in the blood of inner-city children. The study design will test lead levels in five groups of housing with anywhere between no lead contamination to houses with lead contaminates that have not been cleaned up. For two years, the researchers will take periodic blood samples of human subjects, as well as dust and water samples, to measure lead contamination. The families will receive roughly 10% reduction in their rent payments (~$100/month) to encourage their participation. Other lead-poisoning experts, who say they have conducted similar studies on lead abatement, emphasize the importance of this line of research that will save lives in the future.

You are serving on the Johns Hopkins Institutional Review Board (IRB) for this study, and you are developing a checklist of actions that accepts or modifies components of the above research plan. Provide information to the research team on how each aspect below should be formulated. /50

Name	Explanation
Informed Consent	The families need to be told exactly what the experiment is, what benefits it might provide to others and all the risks to them and their children. They need to know what medical treatment is available to them, that it is completely voluntary, they can end it at any time and who to contact with questions.
Selection of Subjects:	The subjects need to be as diverse as possible. Varying ages, sexes, races, ethnicities etc to adhere to the principle of Justice. This also includes varying social & economic statuses as well.
Risk/Benefit Analysis:	All risks should be identified (potential/probabilities and actual) If the subjects have a potential to die or become severly ill, the study should not start. The benefit is great since it will save many lives in the future.
Monitoring and Observation	The IRB will constantly check the progress of the experiment interms of the Health of the subjects, and overall protocol to insure it is still ethically sound. They can end the experiment at any time.
Incentives for Participation	The IRB will monitor the incentives to make sure no coercion is happening. If a family feels that 10% is not enough for the type of risks, the IRB will come up with acceptable options within ethical ~~guidlines~~ guidelines.

31. Conflicts of Interest. Jesse Gelsinger suffers from a genetic liver disease involving a defective protein, but the disease is manageable by diet. He is volunteering for a study at the University of Pennsylvania Institute for Human Gene Therapy; the UPenn research team is researching ways to transport healthy genes to replace faulty genes using common adenoviruses and much will be learned from this study that is extensible to other disease such as cancer. Screening tests show that Jesse Gelsinger's liver is just below the minimal level required under the study criteria, but he is otherwise very healthy, and thus will be placed in the study. The director of the Institute, James M. Wilson, owns stock in Genovo, the company that finances research at the Institute, and he has patents on the gene therapy procedures the Institute is developing. The University's contract with Genovo gives the company rights to gene therapy discoveries in exchange for substantial financial support. Recently, the research team has discovered severe side effects experienced by prior human subjects, similar to the cause of death of monkeys who had undergone a related treatment.

You serve on the Institutional Review Board (IRB) at UPenn for this study that is undergoing its biannual review. As IRB member, define the best course of action by applying the 4As to the study in progress. You are already given the first A of acquiring the facts (above), and you are also given three alternatives (below). Complete the final 2As on the three alternatives and neatly circle your final course of action.

The 4A's: Acquire Facts (given), Alternatives (given), Assessment, and Action 150

(1) Discontinue the study

(2) Formulate an informed consent document that disclose the facts, but leave current research design in place.

(3) Halt the study for 3 years to have the research team reformulate the research protocol

Assessment

(1) From a rights perspective this is the course of action. Jesse has the right not to participate in a study that may kill him. Other stakeholders - James Wilson, Upenn and Genovo don't benefit b/c they might not find the cure. This also eliminates the the conflict of interest between Wilson, Upenn & Genovo (more stakeholders)

(2) This is based on Autonomy + Utilitarianism. Autonomy b/c Jesse has the right to make decisions that concern him + Utilitarianism b/c the research may benefit many people in the future. The conflict of interest still remains.

(3) This is based on duty by the researchers to do no harm (non-maleficence) to Jesse and allows for time to eliminate the conflict.

Action

As a member of the IRB, I would choose option 3. The research should continue at some point because of the benefit to many others but right now the risks are too great for Jesse and there is a very large conflict of Interest. The 3 yrs will allow time for the researchers to possibly get rid of the severe side effects, find a subject healthy enough to participate (Jesse was not healthy enough) and manage the conflict. Wilson needs to disclose his conflict and the IRB needs to find away around it.