Ethics modules

Module History and Ethics karen butlercorrectly answered 7 of 7 questions and received 7 of 7 possible points. Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: An investigator fails to inform subjects about the foreseeable risks in a study of a new drug. Which of the following best describes the ethical principle violated?

Your answer:

Respect for persons.

Correct Answer:

Respect for persons.

Comment:

Implicit in respect for persons is that individuals are autonomous in their decision making and should be provided adequate information prior to making a decision about whether to participate in the research. Justice, Research Integrity and access to research focus more on the research study itself.

Points Earned:

1

Question2: Which of the following lists the three principles discussed in the Belmont Report?

Your answer:

Respect for Persons, Beneficence, Justice.

Correct Answer:

Respect for Persons, Beneficence, Justice.

Comment:

The Belmont Report published in 1979 identifies three basic ethical principles that underlie all human subject research. These principles are commonly called the Belmont Principles. The Belmont Principles are respect for persons, beneficence, and justice.

Points Earned:

1

Question3: An investigator wishes to study lifestyle and diet influences on the risk of developing a specific cancer. The investigator chooses a case-control design with paired lifestyle interviews and a few blood and urine tests and assigns a study manager to identify patients with the diagnosis from the pathology logbook that lists names. The study manager would then ask each patients primary physician for permission to contact the patient. Which of the following is required before the investigator begins the study?

Your answer:

IRB review and approval.

Correct Answer:

IRB review and approval.

Comment:

IRB review and approval based on the pledge outlined in the institutional assurance. The others may be appropriate under some cases and may be institutional requirements.

Points Earned:

1

Question4: The Belmont Report describes all of the following EXCEPT:

Your answer:

The Belmont Report indicates that it is necessary to rigorously avoid conflicts

of interest as an example of the Principle of Justice.

Correct Answer:

The Belmont Report indicates that it is necessary to rigorously avoid conflicts of interest as an example of the Principle of Justice.

Comment:

The Belmont Report defines and delineates between " Practice" and " Research" , describes the concept of " Respect for Person" and provides formulations for the ethical distribution of research benefits and risks (Principle of Justice). The Belmont report does not describe the necessity to effectively manage conflicts of interest as an example of the Principle of Justice.

Points Earned:

1

Question5: In what way did the Beecher article impact research in the United States?

Your answer:

It heightened awareness of problems with unethical research.

Correct Answer:

It heightened awareness of problems with unethical research.

Comment:

The best answer is " heightened awareness". In 1966 Dr. Henry K. Beecher, wrote an article describing numerous research studies with controversial ethics, conducted by reputable researchers and published in major journals. Beecher concluded, " unethical or questionably ethical procedures are not uncommon." Beechers article played an important role in heightening the awareness of researchers, the public, and the press to the problem of

unethical human subjects research.

Points Earned:

1

Question6: Which of the following is an example of how the Principle of Beneficence can be applied to a study employing human subjects?

Your answer:

Determining that the study has a maximally favorable risk vs benefit ratio.

Correct Answer:

Determining that the study has a maximally favorable risk vs benefit ratio.

Comment:

According to the Belmont Report a determination that a study has a favorable risk vs benefit ratio is an example of the Principle of Beneficence.

Points Earned:

1

Question7: Which of the following studies led to the establishment of the National Research Act and ultimately the Belmont Report and Federal regulations for human subject protection?

Your answer:

The Public Health Service syphilis study.

Correct Answer:

The Public Health Service syphilis study.

Comment:

Although the other studies are clear instances of human subjects abuse, it was the publicizing of the PHS study that triggered congressional action.

Points Earned:

1

Module 2: Defining Research with Human Subjects

karen butlercorrectly answered 5 of 5 questions and received 5 of 5 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: According to the federal regulations human subjects are living human beings about whom an investigator obtains:

Your answer:

identifiable private information.

Correct Answer:

identifiable private information.

Comment:

In order to meet the definition of research with human subjects a researcher must obtain data about a living individual through interaction or intervention or obtain individually identifiable private information. Although “ public behavior” may be construed differently from setting to setting, public behavior is, by definition, not private information. Information without identifiers that is publicly available is also not ‘ private identifiable information’ so it too does not meet the definitional requirements. Information that is publicly available is also not considered to involve human subjects even when that information is clearly identifiable (such as that in telephone directories or faculty directories available online to anyone with access to the internet).

Points Earned:

1

Question2: According to the federal regulations, which of the following studies meets the definition of research with human subjects?

Your answer:

A cognitive psychologist proposes recruiting undergraduate students for a computer-based study about the effect of activating mood states on problem solving behaviors.

Correct Answer:

A cognitive psychologist proposes recruiting undergraduate students for a computer-based study about the effect of activating mood states on problem solving behaviors.

Comment:

A cognitive scientist studying the effect of mood states on problem solving behaviors has research question and is interacting with living individuals. Questioning a superintendent of schools to acquire data about the ethnic composition of a school system is asking " about what" questions rather than " about whom" questions. (If a study proposed interviewing the superintendent of public schools about his or her experience in the field of education or about his or her perceptions about the current problems within the school system and possible solutions, the questions would become " about whom.") Analyses of public behavior such as writing for a blog or a newspaper do not meet the definition because there is no interaction or intervention with a human subject and no collection of private information. Finally, in the class exercise described, the intention is pedagogical ï¿½ to learn how to conduct and interview, rather than to answer a research question.

Points Earned:

1

Question3: According to the federal regulations, which of the following studies meets the definition of research with human subjects?

Your answer:

A study of twenty 4th grade classrooms in which researchers ask the schools to systematically vary the time of day reading is taught and collect weekly assessments of reading comprehension for each child over a three-month period.

Correct Answer:

A study of twenty 4th grade classrooms in which researchers ask the schools to systematically vary the time of day reading is taught and collect weekly assessments of reading comprehension for each child over a three-month period.

Comment:

The study in the 4th grade classrooms about the relationship between the time of day reading is taught and reading comprehension does meet the definition of research with human subjects. The study is designed to contribute to generalizable knowledge about student performance and the research question can only be answered using a systematic investigation. Information collected by the play ground designer does not involve any information about human subjects even though it does involve interaction between the designer and school staff. An analysis of aggregate data doesnt involve interactions with living individuals nor the collection of private identifiable data.

Points Earned:

1

Question4: According to the federal regulations, which of the following studies meets the definition of research with human subjects?

Your answer:

A study is proposed about the effects of evoking stereotypes about gender-related differences in math ability on female subjects performance of mathematical tests.

Correct Answer:

A study is proposed about the effects of evoking stereotypes about gender-related differences in math ability on female subjects performance of mathematical tests.

Comment:

In the study of the effects of evoking stereotypes on subsequent performance, the researcher has a research question and will be manipulating the behavior of individuals. An in-house study conducted with the intention of improving a departments mentoring programs is not research with human subjects, but rather program improvement. Receiving data with no identifiers is not research with human subjects because there is no interaction or intervention with a living human being and no collection of private identifiable data. In addition, creating a report for a membership organization does not involve a research question, as defined by the federal regulations, so it too is not research with human subjects.

Points Earned:

1

Question5: According to the federal regulations, which of the following studies meets the definition of research with human subjects?

Your answer:

A developmental psychologist proposes videotaping interactions between groups of toddlers and their care givers to determine which intervention methods most effectively manage aggression.

Correct Answer:

A developmental psychologist proposes videotaping interactions between groups of toddlers and their care givers to determine which intervention methods most effectively manage aggression.

Comment:

The study of passenger lists is a study of individuals who are no longer living. A human subject is a living individual. Questioning individuals to acquire data about the number of newly diagnosed HIV cases is asking " about what" questions rather than " about whom" questions. Conducting a linguistic analysis of comments posted on a public blog involves neither interaction with individuals nor collecting private identified information and thus does not meet the definition of research with human subjects. The study proposed by the developmental psychologist does meet the definition of research with human subjects. It involves interactions with living individuals and is designed to contribute to a field of knowledge.

Points Earned:

1

Module 3: The Regulations and the Social and Behavioral Sciences

karen butlercorrectly answered 5 of 5 questions and received 5 of 5 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: According to the federal regulations, research is eligible for exemption, if

Your answer:

The research falls into one of six categories of research activity described in the regulations.

Correct Answer:

The research falls into one of six categories of research activity described in the regulations.

Comment:

Research is only eligible for exemption if all the activity associated with the research fall into one of six categories of activities described in the federal regulations. The regulations do allow some research with children to be exempt (although institutional policy may not). The duration of the study and the experience of the investigator are not criteria for determining eligibility for exemption.

Points Earned:

1

Question2: Which of the following statements about the relationship between an institution and the institution’s IRB(s) is correct?

Your answer:

Officials of the institution may overturn an IRB approval.

Correct Answer:

Officials of the institution may overturn an IRB approval.

Comment:

If an IRB has disapproved a protocol, that disapproval may not be overturned by an institutional official or anyone at that institution, such as a department

chair. However, even if an IRB has approved a protocol, it may be subject to other reviews at the institution and may be disapproved.

Points Earned:

1

Question3: Continuing review of an approved protocol

Your answer:

Must occur within 12 months of the approval date.

Correct Answer:

Must occur within 12 months of the approval date.

Comment:

Continuing review of an approved protocol must occur within 12 months of the approval date even if no additional risks have been identified. Review by a convened IRB is not always required. Any unanticipated problems must be addressed during the continuing review process, but the review must include other information such as the number of subjects accrued, any relevant recent literature, and a copy of the current consent form.

Points Earned:

1

Question4: In addition to pregnant women, fetuses, and neonates, subparts of the DHHS regulations provide additional protections for which of the following vulnerable populations?

Your answer:

Prisoners.

Correct Answer:

Prisoners.

Comment:

Prisoners are provided additional protections in the DHHS regulations. The DHHS regulations do not have specific additional protections for the elderly, for students, or for persons whose decision-making capabilities are impaired. Investigators may consider and the IRB may require additional safeguards for these populations.

Points Earned:

1

Question5: According to federal regulations, the expedited review process may be used when the study procedures pose:

Your answer:

No more than minimal risk and the research activities fall within regulatory categories identified as eligible.

Correct Answer:

No more than minimal risk and the research activities fall within regulatory categories identified as eligible.

Comment:

Research is eligible for expedited review when it poses no more than minimal risk to the participants and when all the activities fall within categories identified as eligible. Studies with more than minimal risk do not qualify for expedited review even if the subjects are adults, the sponsor is in a hurry, or the study replicates previously approved research.

Points Earned:

1

Module 4 : Assessing Risk in Social and Behavioral Sciences

karen butlercorrectly answered 5 of 5 questions and received 5 of 5 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: If disclosure of a subjects involvement in a specific research study can be potentially harmful to the subject, and the consent form is the only record linking the subject to the research, which of the following would be most helpful:

Your answer:

Obtain a waiver of documentation of informed consent.

Correct Answer:

Obtain a waiver of documentation of informed consent.

Comment:

If the only identifier collected in the course of a study would be the signature on the consent document and the principal source of harm would be a breach of confidentiality, a waiver of documentation of informed consent should be sought.

Points Earned:

1

Question2: What statement about risks in social and behavioral sciences research is most accurate:

Your answer:

Risk may be culturally determined.

Correct Answer:

Risk may be culturally determined.

Comment:

Research in the social and behavioral sciences sometimes does pose risks to

subjects. Risks can be time, situation, and culture specific. What may be a socially sensitive issue or topic at a given time, in a given culture may not be so at another time and/or place. The risk of emotional distress cannot be managed by anonymizing data, but rather by developing a plan to respond to the distress should it occur. Risks must always be minimized to the extent possible, regardless of the potential for benefit.

Points Earned:

1

Question3: Only federally funded projects are eligible for Certificates of Confidentiality.

Your answer:

False

Correct Answer:

False

Comment:

For example, NIH issues Certificates of Confidentiality regardless of the source of funding and even for un-funded research.

Points Earned:

1

Question4: An investigator wishes to study generational differences in coping mechanisms among adults who experienced abuse as children. Adequate measures will be instituted to obtain informed consent and ensure that there is no breach of confidentiality. The most likely additional risk is that subjects may:

Your answer:

Experience emotional or psychological distress.

Correct Answer:

Experience emotional or psychological distress.

Comment:

Subjects may experience emotional or psychological distress. The fact that the subjects have consented to participate in the study makes it unlikely that they would feel that their privacy was being invaded. Because confidentiality procedures have been built into the protocol it is also unlikely that the subjects might lose legal status or employment.

Points Earned:

1

Question5: The primary purpose of a Certificate of Confidentiality is to:

Your answer:

Protect identifiable research information from forced disclosure.

Correct Answer:

Protect identifiable research information from forced disclosure.

Comment:

Certificates of Confidentiality protect sensitive information provided by research subjects from civil, criminal, or administrative subpoena.

Points Earned:

1

Module 5 : Informed Consent

karen butlercorrectly answered 4 of 4 questions and received 4 of 4 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: A therapist at a free university clinic treats elementary school children with behavior problems who are referred by a social service agency. She is also a doctoral candidate who proposes to use data she has already obtained about her clients for a research project using case studies. Which of the following statements is true?

Your answer:

The parents of the children might feel pressure to give permission for the therapist to use their childrens data because of the free service she provides.

Correct Answer:

The parents of the children might feel pressure to give permission for the therapist to use their childrens data because of the free service she provides.

Comment:

When a care provider becomes a researcher, both the child clients and their parents may not feel free to choose not to participate in the provider’s study. A researcher who is also a care provider needs to be very clear that a decision not to participate in a study, or to allow records to be used, will not affect the care provided in the future. The fact that the therapist has access to her clients’ records as a clinician does not entitle her to use information in the records for research purposes without parental permission and child assent. A school authority’s permission to conduct the research does not replace the need for permission or assent. Finally, the children’s right to choose cannot be overridden in the pursuit of an indeterminate community interest.

Points Earned:

1

Question2: A researcher proposes conducting a school-based study with adolescents about peer relationships and academic achievement. Which of the following recruitment strategies would minimize undue influence on students' choices about whether to participate?

Your answer:

The researcher is given a few minutes of class time, when the teacher is out of the room, to describe the study and gives all students copies of the permission and assent form

Correct Answer:

The researcher is given a few minutes of class time, when the teacher is out of the room, to describe the study and gives all students copies of the permission and assent form

Comment:

Undue influence can occur when someone in a position of authority over potential subjects asks them to participate. Parents and students receiving a letter from the school principal asking them to participate in a study may feel that it is in their best interests to participate even if they are assured that the decision to participate will not affect their grades or standing in the school. This may be particularly true if it is perceived that the principal will know who decided to participate. Similarly if teachers choose potential subjects or ask students to raise their hands in class, students may not feel entirely free to decline. If a researcher visits a classroom to describe a study and ask all students to consider participating, because he or she has no authority over the students and cannot make decisions that would effect their future, such as awarding grades, the potential for undue influence

would be minimized.

Points Earned:

1

Question3: A waiver of the requirement for documentation of informed consent may be granted when:

Your answer:

The only record linking the subject and the research is the consent document and the principal risk is a breach of confidentiality.

Correct Answer:

The only record linking the subject and the research is the consent document and the principal risk is a breach of confidentiality.

Comment:

The requirement to document informed consent can be waived if the only record linking the subject and the research is the consent document and the principal risk is a breach of confidentiality. The requirement may also be waived if the study poses no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context. With regard to non-English speakers, if documentation is required, investigators must provide informed consent materials in the subjects language. If a researcher anticipates that subjects might be embarrassed by questions, this concern should be addressed in the consent process. Finally, identifying secure storage space for consent forms is an investigators responsibility.

Points Earned:

1

Question4: As part of the consent process, the regulations require

researchers to:

Your answer:

Provide potential subjects with information at the appropriate reading comprehension level.

Correct Answer:

Provide potential subjects with information at the appropriate reading comprehension level.

Comment:

Researchers must provide information to subjects in a manner comprehensible to subjects. Therefore, the material must be written at the appropriate reading comprehension level. Researchers may not impose penalties for non-participation because to do so would violate the ethical principle of respect for persons. In some circumstances it may be appropriate to ask subjects to discuss the research with their families before making a decision about whether to participate, but it is not a regulatory requirement. Finally, researchers are not required to disclose their research hypothesis because to do so could invalidate their research results.

Points Earned:

1

Module 6 : Privacy and Confidentiality

karen butlercorrectly answered 4 of 4 questions and received 4 of 4 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: When a focus group deals with a potentially sensitive topic, which

of the following statements about providing confidentiality to focus group participants is correct?

Your answer:

The researcher cannot control what participants repeat about others outside the group.

Correct Answer:

The researcher cannot control what participants repeat about others outside the group.

Comment:

It is not possible for a researcher to promise confidentiality in a focus group setting. Participants may choose to repeat sensitive information outside the group setting even if they have signed confidentiality agreements. This is true even if the participants know each other. Using pseudonyms in the report does not remove concerns about what group members might say outside the group.

Points Earned:

1

Question2: A researcher proposes to study the effect of erectile dysfunction on romantic relationships. He plans to recruit and interview subjects at a clinic that offers free prostate exams. He will post a flyer in the waiting room that says that he is interested in studying mens health and romantic relationships. During the consent process he will inform potential subjects that he will be asking personal questions including questions about erectile function. Which of the following confidentiality procedures would best protect the privacy of the subjects during the interview process?

Your answer:

Conducting the interviews in a private room.

Correct Answer:

Conducting the interviews in a private room.

Comment:

If the interview does not take place in a private room, the interview may be overheard by anyone in the waiting room or other public space in the clinic. If the interview is not private, procedures such as recording ages and income in ranges or asking subjects not to identify their partners would not protect the subjects privacy during the interview process. Similarly, if the interview is not held in a private setting, the researchers decision to take notes rather than record the interview is not a strategy that would provide privacy.

Points Earned:

1

Question3: Which of the following confidentiality procedures would provide the highest level of protection of individually identifiable information in a longitudinal study about illegal activities:

Your answer:

Securing a Certificate of Confidentiality.

Correct Answer:

Securing a Certificate of Confidentiality.

Comment:

Although data encryption, using pseudonyms, and waiving documentation of consent, provide data protection, the researcher can link individuals to their responses. Therefore, the data are vulnerable to subpoena in civil, criminal, and administrative court proceedings. Unless the researcher has a Certificate of Confidentiality, he or she may be compelled to release individually

identifiable information about research subjects. The Certificate provides the highest level of protection.

Points Earned:

1

Question4: Which of the following statements about Certificates of Confidentiality is true?

Your answer:

They allow investigators to refuse to disclose information about individual research subjects.

Correct Answer:

They allow investigators to refuse to disclose information about individual research subjects.

Comment:

Certificates of Confidentiality are designed to provide legal recourse to researchers receiving subpoenas requiring them to disclose confidential, potentially damaging information about research participants. They may be used in civil, criminal, administrative, legislative, or other proceedings whether at the federal, state, or local level. They may be secured for any research regardless of funding. They are not designed to protect information about researchers.

Points Earned:

1

Module 7 : Research with Prisoners

karen butlercorrectly answered 4 of 4 questions and received 4 of 4 possible points.

Scroll down to review the quiz questions and the explanation of the answers.

Links to the next module or gradebook are located at the bottom of the page.

Question1: An investigator is examining the quality of life for prisoners who are HIV positive. The researcher plans to use standardized survey instruments followed by an interview. Neither the survey nor the interview questions are probing about the offenders past life but maintain a focus on current life situation in the prison. The IRB must ensure that:

Your answer:

Confidentiality of the prisoners health status is maintained.

Correct Answer:

Confidentiality of the prisoners health status is maintained.

Comment:

By participating in the research, it is possible that subjects will become publicly identified as HIV positive. This breach of confidentiality could lead to negative consequences for the prisoner. One method for the investigator to preserve this confidentiality is to interview a larger sample of offenders, some who are HIV positive and some who are not. The survey should be validated and reliable. It does not have to be standardized. If the research is behavioral only, there is no need for a medical doctor. The prisons HIV testing procedures are not in the purview of the IRB.

Points Earned:

1

Question2: An investigator is examining the relationship between family contact/visitation and depression in mothers recently admitted to a state prison. The researcher will use the data to develop support programs for prison mothers. The sample will be limited to first offenders with children

under the age of five years. Research subjects will be given a basket of toys to use at their childrens first visit that the children can then take home. In assessing this proposal, the IRB needs to determine that the toys are:

Your answer:

Not an excessive incentive.

Correct Answer:

Not an excessive incentive.

Comment:

Mothers who may have recently separated from their children may find the prospect of doing something special for their children more important than making a considered decision about becoming a research subject. Thus the toys may be an excessive incentive to participate.

Points Earned:

1

Question3: Which of the following statements about prison research is true?

Your answer:

Researchers may study the effects of privilege upgrades awarded by the prison.

Correct Answer:

Researchers may study the effects of privilege upgrades awarded by the prison.

Comment:

Studies of the effects of processes of incarceration are allowed under the regulations. Therefore, researchers may study the effects of privilege upgrades awarded by the prison. The regulations do not prohibit payment of prisoners as long as the amount of compensation would not constitute undue

influence to participate. (Correctional institutions may prohibit payment.) The decision to participate in research may not be considered during parole hearings as this practice would clearly constitute undue influence to participate. The regulations require that IRBs determine that risks involved in research with prisoners are commensurate with risks that would be accepted by non-prison volunteers.

Points Earned:

1

Question4: A graduate student wants to examine the effect of print media versus televised media on individuals position on several social issues. Her advisors neighbor is the superintendent of a local work release facility and will allow the graduate student access to the prison population to help her quickly accrue subjects. The subjects will be asked for 15 minutes of their time. The risks appear to be no more than minimal. The IRB would most likely?

Your answer:

Not approve this project because the prisoners are merely a population of convenience.

Correct Answer:

Not approve this project because the prisoners are merely a population of convenience.

Comment:

Factors such as the level of risk and proposed facility are irrelevant if the prison population is simply a population of convenience as it is in this case. Research taking place in prisons must be material to the lives of the prisoners. Therefore, according to the regulations, an IRB could not approve

this protocol.

Points Earned:

1

Module 8 : Research with Children

karen butlercorrectly answered 4 of 5 questions and received 4 of 5 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: Which of the following statements most accurately describes the requirement for the documentation of minors’ assent to participate in research?

Your answer:

Documentation is required unless waived by an IRB.

Correct Answer:

Federal regulations do not require the documentation of minors’ assent.

Comment:

TThe federal regulations do not require that child assent be documented. Therefore it is not necessary to request a waiver of a requirement to document assent. An IRB will determine whether and how documentation is required for a particular study. The document does not require parental input or parental review.

Points Earned:

0

Question2: Fourteen-year-old students in an after-school program will be asked to complete a questionnaire that asks about their use of illegal drugs.

Students will be identifiable through the use of a key linking a unique ID number with names. Which of the following statements about minor assent is accurate?

Your answer:

Active assent from each student is required before they can participate in the study.

Correct Answer:

Active assent from each student is required before they can participate in the study.

Comment:

According to the regulations, active assent is required for minors participating in research. The requirement may be waived by an IRB in accordance with criteria provided in the regulations; however, mere absence of dissent does not meet the criteria. Parental or district-based permission is not sufficient when minors are mature enough to give active assent are participating in research.

Points Earned:

1

Question3: A researcher asks an IRB to waive the requirement for parental permission for a study conducted in schools because the nature of the research requires participation of all the children present in classrooms on the day the research will take place. Assuming that the basic research design could be approved by the IRB and the school, which of the following requirements must be met before an IRB could waive parental permission?

Your answer:

The research must pose no more than minimal risk.

Correct Answer:

The research must pose no more than minimal risk.

Comment:

One of the four criteria for waiving parental permission is that the research must pose no more than minimal risk. Although it may be appropriate to notify parents that the study is taking place, and many researchers do so, it is not required by the regulations when a wavier of parental permission has been approved. While children must provide assent to participate, depending upon the age of the children there are multiple strategies for accommodating children who do not want to participate other than alternate classroom activities. It is not required that an independent consultant approve waivers of parental permission.

Points Earned:

1

Question4: A study that involves interviews of adults is eligible for expedited review. The researcher wants to add an adolescent population (aged 12 to 17) to the study and has designed a parental permission and assent process. No additional changes are planned. Which of the following statements is accurate?

Your answer:

Unless the nature of the questions would raise the level of risk to more than minimal for adolescents, the research would still qualify for expedited review.

Correct Answer:

Unless the nature of the questions would raise the level of risk to more than minimal for adolescents, the research would still qualify for expedited

review.

Comment:

Research involving children may be expedited if the level of risk is no more than minimal and if the research falls into a category of research identified as eligible for expedited review. Therefore, unless the nature of the topic would raise the level to more than minimal risk to the adolescent subjects, the study previously approved for adults through expedited review procedures would also be eligible for expedited review. It is not necessary for adolescents to have obtained some adult rights through emancipation procedures, nor must the reading level of the subjects be predetermined in order for a study involving minors to be eligible for expedited review. Consent forms, including the readability of the information, must always be tailored to the particular subject population of a study.

Points Earned:

1

Question5: According to Subpart D, research with children may be eligible for exemption when:

Your answer:

The research involves educational testing.

Correct Answer:

The research involves educational testing.

Comment:

Subpart D restricts the use of exemptions when children are research subjects. Research that involves interviews, surveys, or participant observation with children as subjects is not eligible for exemption.

Points Earned:

1

Module 9 : Research in Public Elementary and Secondary Schools

karen butlercorrectly answered 4 of 4 questions and received 4 of 4 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: Which federal regulation governs how researchers can obtain data about subjects school disciplinary status?

Your answer:

The Family Education Rights and Privacy Act.

Correct Answer:

The Family Education Rights and Privacy Act.

Comment:

A students disciplinary status is part of his or her school record. In accordance with FERPA schools must usually have written parental permission before they can release data from school records to researchers. The Protection of Pupil Rights amendment is concerned with the kinds of questions that may be included in surveys and interviews with minor school children. The No Child Left Behind Act is a specific amendment to PPRA that gives parents additional rights over the content of research materials. Subpart D of 45 CFR 46 is concerned with the rights of children as research subjects and does not regulate school systems.

Points Earned:

1

Question2: According to Subpart D, which of the following research activities

with children would qualify for an exemption?

Your answer:

Educational testing

Correct Answer:

Educational testing

Comment:

Subpart D, Additional DHHS Protections for Children, specifically prohibits the use of exemption for research involving survey procedures, interview procedures, or participant observation when children are research subjects.

Points Earned:

1

Question3: The purpose of the Family Education and Privacy Rights Act (FERPA) is to:

Your answer:

Provide parents certain rights over their childrens educational records.

Correct Answer:

Provide parents certain rights over their childrens educational records.

Comment:

The purpose of FERPA is to give parents certain rights with regard to the release of their childrens educational records. School personnel such as teachers, counselors, and principals may access student records for legitimate school functions. Generally, schools must have written permission from a parent before releasing any identifiable information form a students record.

Points Earned:

1

Question4: Parental notification, in lieu of active parental permission, is allowed when:

Your answer:

An IRB has approved a waiver of the requirement for parental permission.

Correct Answer:

An IRB has approved a waiver of the requirement for parental permission.

Comment:

Parental permission must be secured or waived in accordance with criteria established by federal regulation. When a waiver has been approved, investigators may wish to, and IRBs may require, that parents be notified that the study will take place, giving them the opportunity to withdraw their children from the study. Parental notification can never be substituted for active parental permission if the criteria for a waiver have not been met.

Points Earned:

1

Module 10 : International Research

karen butlercorrectly answered 4 of 4 questions and received 4 of 4 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: Which of the following activities constitutes engagement in research?

Your answer:

Obtaining informed consent and conducting research interviews.

Correct Answer:

Obtaining informed consent and conducting research interviews.

Comment:

If an institution obtains informed consent and conducts research interviews it is engaged in research.

Points Earned:

1

Question2: The only persons from whom consent should be sought are the research subjects themselves.

Your answer:

False

Correct Answer:

False

Comment:

In non-U. S. communities, people other than the potential subject may be required to give consent. Such individuals could include a spouse, a head of household, or a community leader. In some cases, consent or permission from these individuals may be needed before the potential subject is approached.

Points Earned:

1

Question3: The age of majority in international research is determined by the

Your answer:

Laws, customs, and norms in the area in which the research will be conducted.

Correct Answer:

Laws, customs, and norms in the area in which the research will be conducted.

Comment:

The age of majority should be the recognized age of majority in the country or region where the research takes place.

Points Earned:

1

Question4: Which of the following is the LEAST important activity when protecting human subjects in international research?

Your answer:

Assessing local transportation conditions

Correct Answer:

Assessing local transportation conditions

Comment:

It is essential that researchers have sufficient knowledge of the local research context to be able to design and carry out research in a way that protects the rights and welfare of the subjects. This includes knowledge about unique risks subjects might face given the local socio-economic conditions. Community consultation is particularly important when research has the potential to affect the community as a whole and when there are gatekeepers for the community, e. g. a tribal council.

Points Earned:

1

Module 11 : Internet Research

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the

page.

Question1: If a researcher conducting non-exempt research using an on-line survey provides the elements of informed consent on a screen and asks potential participants to -click- to the screen containing the survey if they wish to be in the study, what must the researcher request from his or her IRB?

Your answer:

A waiver of the requirement to document informed consent.

Correct Answer:

A waiver of the requirement to document informed consent.

Comment:

If the researcher has provided the elements of consent at the survey site for potential participants to read, he or she need not secure a waiver of the requirement to provide the elements. However, this method of securing consent does not provide the researcher with a signed document indicating subjects’ agreement to participate. Therefore, the researcher must obtain a waiver of the requirement to document consent.

Points Earned:

1

Question2: SSL is a protocol designed to provide secure communications via the Internet.

Your answer:

True

Correct Answer:

True

Comment:

SSL, short for Secure Sockets Layer, is a protocol developed by Netscape for transmitting private documents via the Internet.

Points Earned:

1

Question3: Which of the following on-line research strategies raises the most concerns regarding the ethical principle of respect for persons and the corresponding federal regulations requiring informed consent?

Your answer:

A researcher proposes to join a moderated support group for cancer survivors posing as a survivor. She plans to insert comments to see how the members respond.

Correct Answer:

A researcher proposes to join a moderated support group for cancer survivors posing as a survivor. She plans to insert comments to see how the members respond.

Comment:

The study in which the researcher pretends to be a cancer survivor involves deception and research without any informed consent process. Therefore, the study raises concerns about the ethical principle of respect for persons. Any compromise of the principle should be justified by any scientific benefit to be derived from the study. When a support group or a blog is open to any and all readers, it can be argued that the communications posted are not intended to be private and can therefore be observed and recorded without informed consent. The researcher studying interracial asdoptees used the Internet in a manner comparable to posting a flyer on a bulletin board.

Points Earned:

1

Question4: Consent to participate in research is an ongoing process. Which of the following strategies would help ensure that participation in a survey about a sensitive personal topic remains voluntary throughout a study?

Your answer:

Designing the survey so that subjects are not forced to answer one question before going to the next

Correct Answer:

Designing the survey so that subjects are not forced to answer one question before going to the next

Comment:

Voluntary participation in research includes not only the right to withdraw from a study at any time but the right to choose not to answer questions that a subject might find intrusive or would prefer not to answer for any reason. On-line surveys that force subjects to answer one question before going to the next compromise the ethical principle of autonomy. Providing a privacy policy, and a description of the survey are important, but they do not address the concern. The function of debriefing is to provide information about a study when the study is completed and does not address voluntary participation.

Points Earned:

1

Question5: E-mail messages are secure communications.

Your answer:

False

Correct Answer:

False

Comment:

Some companies have access to all employee e-mail. Family members may read each others mail. Keystroke loggers installed on personal computers may compromise the security of all communications.

Points Earned:

1

Module 12 : HIPAA and Human Subjects Research

karen butlercorrectly answered 2 of 2 questions and received 2 of 2 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: A consent for research under the Common Rule is the same as an authorization for disclosure of PHI under the Final Privacy Rule.

Your answer:

False

Correct Answer:

False

Comment:

Correct. Although the Final Privacy Rule provides that these two documents can be combined, they address two different issues.

Points Earned:

1

Question2: As part of its commitment to evidence-based medicine, Medical School Alpha wants to ensure that its students and residents will be able to

understand and evaluate the results of future research. Accordingly, the school requires each student and resident to develop a research protocol, collect data on living and deceased patients, analyze the data and report the results. Many of these studies will involve medical record or chart reviews, although patients have never explicitly agreed to have their medical records used in this way. Does the Final Privacy Rule make these chart reviews improper without further IRB or Privacy Board action? Consider each of the answers and choose the most appropriate one.

Your answer:

Yes, the IRB or Privacy Board must grant a HIPAA compliant waiver of authorization for this undertaking because the research is not authorized by a patient, not a review preparatory to research and does not solely use decedent information.

Correct Answer:

Yes, the IRB or Privacy Board must grant a HIPAA compliant waiver of authorization for this undertaking because the research is not authorized by a patient, not a review preparatory to research and does not solely use decedent information.

Comment:

The best answer is D. It indicates HIPAAs requirements for chart reviews such as this. It is highly unlikely that a medical record would contain de-identified data about a patient, thereby exempting the research activity from HIPAA compliance. That is, the link between PHI and an individuals identity would likely be seen by the researcher reviewing the chart. Therefore, proper research access to medical charts by researchers would require an IRB or Privacy Boards waiver of authorization. This waiver is required because the

research is not authorized by a patient, is not a review preparatory to research and does not solely use decedent information. Note that HIPAA, in requiring an IRBs approval for " waiver of consent," uses this well-known Common Rule term – even as The Final Privacy Rule establishes waiver criteria different than those in 45 CFR 46; these criteria are to be evaluated by an IRB or Privacy Board in approving a HIPAA-compliant waiver of authorization.

Points Earned:

1

Module 13 : Workers as Research Subjects – A Vulnerable Population

karen butlercorrectly answered 4 of 4 questions and received 4 of 4 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: When a research project includes the collection of biological samples, all planned future uses of the samples, identifiers, and the data obtained from the samples, must be fully explained to the research subject.

Your answer:

True

Correct Answer:

True

Comment:

Genetic information has the potential to cause significant harm to research subjects if inappropriately disclosed, including harm to a subjects privacy, social standing, family obligations, employment/employability or

insurance/insurability.

Points Earned:

1

Question2: When workers are asked to participate in a research study, vulnerabilities related to the subjects employment may include:

Your answer:

All of the above

Correct Answer:

All of the above

Comment:

Workers who serve as research subjects at their place of employment are vulnerable to numerous kinds of pressure from their co-workers, unions and employers. Pressure can be applied to workers in subtle ways such as an employer who comments that if the research concludes that the organization is spending more on healthcare than other similar organizations, there may be lay-offs, etc.

Points Earned:

1

Question3: Researcher access to confidential records adds to the vulnerability of workers who participate in workplace studies. Inappropriate release of identifiable private information could adversely affect a workers retention of a job, insurance or other employment related benefits. To avoid or minimize these risks, the study design must include adequate safeguards to protect the confidentiality of the information collected. A plan for the proper management of study data and records should clearly define:

Your answer:

All of the above

Correct Answer:

All of the above

Comment:

Principal investigators must recognize that the primary harm in social and behavioral research is the breach of confidentiality. This risk is especially poignant when the data being collected involves an employees experiences at their place of employment, particularly given employers on-going efforts to reduce healthcare costs by getting rid of employees who they believe will cause their healthcare insurance premiums to rise.

Points Earned:

1

Question4: Vulnerable persons are those who are less able to defend themselves than other persons in a given situation. The Common Rule (45 CFR 46) has specific requirements for the following vulnerable populations, except:

Your answer:

Workers

Correct Answer:

Workers

Comment:

The common rule does not classify workers as a vulnerable population. The categories of vulnerable populations explicated in the Common Rule are Pregnant Women, Human Fetuses and Neonates (Subpart B), Prisoners (Subpart C) and Children (Subpart D).

Points Earned:

1

Module 14 : Conflicts of Interest in Research Involving Human Subjects

karen butlercorrectly answered 2 of 2 questions and received 2 of 2 possible points.

Scroll down to review the quiz questions and the explanation of the answers. Links to the next module or gradebook are located at the bottom of the page.

Question1: Current Public Health Service regulations require investigators to disclose details regarding financial conflicts of interest to:

Your answer:

designated institutional officials

Correct Answer:

designated institutional officials

Comment:

Under current rules, investigators are required to report " significant financial interests" to designated institutional officials. The institution is required to report the existence of conflicts of interest - but not the substantive details - to the funding agency, but conflicts are managed internally according to discretionary policies and procedures developed by each institution. It should be noted however that the 2000 revisions to the Declaration of Helsinki lists " sources of funding" among the items to be disclosed to subjects. In addition, the March 2003 Department of Health and Human Services Draft Guidance suggests that IRBs may determine that information regarding conflicts of interest should be required as part of the consent process.

Points Earned:

1

Question2: The most important ethical concerns relating to conflicts of interest in research are (choose one answer):

Your answer:

ensuring the soundness of science and the protection of human subjects

Correct Answer:

ensuring the soundness of science and the protection of human subjects

Comment:

The most important ethical concerns relating to conflicts of interest are the preservation of sound science and the protection of human subject-participants. In fact, the two are related; ensuring soundness science is integral to protecting human subject-participants and those who use the products of science. (a) is incorrect. Research needs human volunteers, but the concern about their availability is a practical rather than ethical matter. (c) is incorrect. Researchers whose primary employer is not a private sponsor of research have a fiduciary responsibility to human subjects and to the public trust that has ethical priority over self-interested contracts.

Points Earned:

1

Module 15 : Northcentral University

No module quiz here, just a survey