IRB Challenge

|  |  |  |
| --- | --- | --- |
| https://t1.ftcdn.net/jpg/00/78/45/74/500_F_78457422_GhW7k9d8Eq99kG9UhXxwVxX435SyEoNL.jpg |  |  |
| **Category: Research Subjects**  A research subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) their identifiable private information. | **Level** | **answer** |
| Vulnerable subjects require special protection. A vulnerable subject may be:  a.      A person who has limited intellectual capacity  b.      A person who is a prisoner  c.      A person who has limited purchasing power  d.      A person under the age of consent  e.      A person who is physically handicapped | 1 | all |
| A vulnerable subject is a person who has diminished capacity to give consent. | 1 | T |
| College students are considered vulnerable subjects because they have little experience with research. | 2 | F |
| Studies must always include all demographic subject groups regardless of the research aims. | 2 | F |
| It’s OK to run an experiment with greater than minimal risk as long as the subject incentive is high. | 3 | F |
| Research studies involving prisoners are almost always exempt because the subjects have state supported healthcare. | 3 | F |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| https://t2.ftcdn.net/jpg/00/38/93/91/240_F_38939108_g0d0WVxfQ5Jx8eFHFpZ9jfOCXdMMXYb4.jpg |  |  |
| **Category: Research Investigators**  Research Investigators use a systematic process to collect and analyze information to increase understanding of a topic or issue. | Level | answer |
| The Principal Investigator (PI) develops the research methodology but is rarely responsible for all activities associated with the conduct of a research project, | 1 | F |
| All investigators on the study team are required to have current certification in the PEERRS training in human subjects protection. | 1 | T |
| When a student is serving as the Principal Investigator (PI) they must have a faculty advisor who takes responsibility for conduct of the research. | 2 | T |
| PIs should provide a review of related research when describing the justification for the research design. | 2 | T |
| PIs must list only the top 3 risks and benefits and show how these risks will be minimized. | 3 | F |
| Even when specific tasks are delegated, the PI remains ultimately responsible for proper conduct of the study and fulfillment of all associated obligations. | 3 | T |
|  |  |  |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **IRB** |  |  |
| **Category: IRB**  An Institutional Review Board (IRB) is a committee that performs ethical review of proposed research with human subjects. | Level | answer |
| The role of the IRB is to:  -Protect research subjects and ensure their well being  -Protect students from unethical faculty  -Protect faculty from university administration | 1 | Protect subjects |
| The UM online IRB application system is called  -eIRBapply  -eSubjectProtection  -PEERRS  -Proposal Management  -eResearch  -eRespectSubjects | 1 | eResearch |
| The IRB has faculty, students and staff as members. | 2 | F |
| To serve on the IRB you must be a tenure track faculty member. | 2 | F |
| One of the responsibilities of the IRB is to review the scientific merit of the study. | 2 | T |
| The IRB does not have a quorum unless the community member is present at the meeting. | 3 | F |

|  |  |  |
| --- | --- | --- |
| http://photos.gograph.com/thumbs/CSP/CSP992/k13638234.jpg |  |  |
| **Category: Research Data**  Research Data is information collected from or about research subjects that is personally identifiable. | **level** | **answer** |
| If a travel drive with personally identifiable data stored on it is lost the PI must notify the IRB immediately. | 1 | T |
| File encryption is difficult and therefore optional in most cases. | 1 | F |
| Because data is often difficult to collect once the study is over researchers can always keep data indefinitely for further research. | 2 | F |
| Use of the internet and cloud computing makes it easy to secure personally identifiable data. | 2 | F |
| UM researchers do not need to be concerned about data security because the U has a firewall. | 3 | F |
| To protect subject identity PIs can use other identifying info instead of a person’s name, like a driver’s license number. | 3 | F |

|  |  |  |
| --- | --- | --- |
| http://wiki.dpconline.org/images/f/f3/Template_clipboard.png |  |  |
| **Category: Consent**  Research Subjects must willingly consent to be participate in the research. | Level |  |
| Obtaining consent  -Is the process of signing a document  -Is a process that includes discussion and a chance to ask questions | 1 | Disc/q |
| The consent form should be written with the reading level of the potential subjects in mind. | 1 | T |
| Consent Form (check all that apply)  a.       Protects patient’s rights  b.      Informs a potential research subject about the procedures of the research  c.       Must state that participation is voluntary  d.      Is legally binding- once a subject signs they must participate in the research | 2 | A,b,c |
| A person under 18 can sign a consent form if the risk is minimal. | 2 | F |
| A person under 18 can sign a consent form if the study is exempt. | 2 | F |
| Child assent is all that is needed if the parental permission is hard to get. | 2 | F |
| Child assent can be verbal. | 2 | T |
| Waiving the need for a consent form is never allowed. | 3 | F |

|  |  |  |
| --- | --- | --- |
| http://www.fns.usda.gov/sites/default/files/images/regulatory.jpg |  |  |
| **Categories- regulations** | level | answer |
| The Office of Human Research Protections (OHRP) is the Federal office providing leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research. |  | |
| HIPAA  -Is the plural of hippocampus  -Is a set of regulations for hospital experimental drug management  -Is a set of regulations for patient record confidentiality  -Is what happens when your hips grow larger than your shoulders | 1 | Patient confidentiality |
| To meet the federal definition for research the study must  -Use a systematic approach to data collection  -Use as many data collection methods as possible  -Use federal funds | 2 | Systematic approach |
| If the risk of the study is greater than minimal risk, the study would not be allowed. | 2 | F |
| When a research study involves children as subjects the federal regulations state the IRB needs to document whether or not it is sufficient to obtain only 1 parent’s signature | 2 | T |
| The “Common Rule” covers common research procedures but not experimental ones. | 2 | F |
| Emergency use of an investigational drug or device is never allowed. | 3 | F |

|  |  |  |
| --- | --- | --- |
| https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/InstitutionalReviewBoard/PublishingImages/policy-pyramid.jpg |  |  |
| **Category: Procedures**  IRB procedures are the ways in which a PI and the IRB interact. | Level | answer |
| When an adverse event occurs during a research project the PI has 6 months in which to report the incident to the IRB. | 2 | F |
| If a PI wants to change some of the ways in which the study will be carried out sending a detailed email to the IRB staff is sufficient | 1 | F |
| An unanticipated event is one where an incident occurs before the research begins. | 2 | F |
| When someone new joins the study team the PI needs to submit an amendment form to the IRB and get approval before the new person can start working on the study. | 2 | T |
| The roles and responsibilities of research investigators are governed by individual departments. | 2 | F |
| The screening process to ensure subjects meet the selection criteria is not considered part of the research. | 3 | F |

|  |  |  |
| --- | --- | --- |
| What are ethics and what have they got to do with me and my research? |  |  |
| **Category- Research Ethics**  Ethical standards promote the **values that are essential to interacting with human subjects** such as trust, accountability, mutual respect, and fairness. | Level | Answer |
| The Belmont Report is an annual report of IRB activities. | 1 | F |
| Responsible researchers avoid intentional misconduct such as falsification, fabrication and plagiarism. | 1 | T |
| The 3 principles of the Belmont Report are  -Truth, Justice and Incentives  -Oversight, Enforcement and Beneficence  -Respect for Persons, Beneficence, Justice  -Fairness, Transparency, Equality | 2 | Respect for Persons, Beneficence, Justice |
| If information becomes available during the course of the study that might impact a subject’s willingness to serve as a subject it is acceptable to keep this information private until the study is completed. | 2 | F |
| The Tuskegee Study was a clinical trial examining the health of the Tuskegee Airmen’s exposure to chemical warfare. | 2 | F |
| Deception in research is never allowed under any circumstances. | 3 | F |