Dear Investigator,

CCHHS Department of Research & Regulatory Affairs

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Thank you for your interest in the human participant research self-guided tutorial. This tutorial is intended to help you evaluate your familiarity with federal regulations and CCHHS policy concerning the use of human participants in research. Successful completion of the tutorial will also result in certification that you have received human participant research training.

The tutorial consists of 25 multiple choice questions. The answers to the questions are based on material in the Guide book first distributed to all researchers November, 1999. A Revision of the Guidebook is available by email request to: bdonoval@cookcountyhhs.org.

The questions are intended to direct your attention to the kinds of matters that come up when you are doing human subject research. The idea is for you to consider these matters, possibly research the “correct” answers, or discuss them with colleagues—as you would if they came up in you human subject research. At present, we have one session per week. If the time is not good for you, you may suggest a time for the next session. We would love to meet you. Please bring your CCHHS ID. We cannot certify anyone without ID.

Please call Betty Donoval (312) 864-4821 with any questions.

**Training Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**I have completed this tutorial myself. (It is OK to confer with colleagues but not to have someone else complete it for you)**

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1. The project coordinator of a study tracking children’s growth learns from the coordinating center that the data submitted included each child’s date of birth instead of the age as requested.
2. There is no problem because the data were entered directly into a secure website so there is no opportunity for a data breach.
3. As long as there are no “sensitive data,” there is no problem.
4. This is OK, because the coordinating center is a “covered entity”
5. All of the above
6. None of the above
7. Dr. Harrison’s research to reduce home conditions that aggravate asthma requires that Research Assistants visit subjects’ homes and review possible asthma triggers. The Research Assistants (RAs) complete subject data collection on each visit and enter it after the visit on the computer. How should these data be handled?
8. The RA should keep all forms and computers in his locked office at JSH. Only the newly collected data should be carried.
9. He should leave the computer in the car with the forms and enter the data between visits.
10. He should carry the forms on his person but the computer may be left in the locked car.
11. Any subject data that is carried in the car must be removed with him each time he leaves the car.
12. Dr. Astor is doing a study in which he is tracking the occurrence of a new virus by the patient’s zip code, date of hospitalization, and country of origin.

1. This is not really research because it is epidemiology.
2. The study is exempt because he is not recording any identifiers on the patients.
3. The study has no identifiers according to 45CFR46 (the “IRB” regulations) but participants are identified according to the HIPAA Privacy Rule.

1. Dr. Wood uses a survey tool to assess how ready his patients are adhere to a medication regimen. A colleague suggests that he analyze the surveys and publish an abstract to guide other practitioners. Which is true?
2. Dr. Wood may publish the abstract however, if he wants to publish a full journal article or make a presentation, he must first submit it to the IRB.
3. He should send a copy of the abstract to the IRB, if it is accepted.
4. Dr. Wood needn’t contact the IRB at all because these are clinical data
5. Analyzing the clinical data to come to a conclusion is research and must be submitted to the IRB before Dr. Wood begins.
6. Dr. Randolph wants to conduct a chart review study of all adult patients admitted to the hospital because of chest pain during the year 1999. The goal is to compare outcomes between patients with and without a history of cocaine use. Names will not be abstracted but the medical record numbers will be. Since the research project involves a review of existing medical records and the only identifying information that's collected is the medical record number, this study:
7. May be exempted from review by any member of the IRB;
8. Is probably exempt, but a formal request is necessary;
9. Would not be exempt from IRB review, because the medical record number can be linked to the patient’s name.
10. Dr. LaSalle is carrying out a study of a promising new treatment for middle ear infection. She is concerned because, for many of the children she would like to treat, only one parent seems to be available. She knows that parental permission is required to enroll children in research, but she doesn't know if it is acceptable to get the permission of only one parent. What is adequate parental permission for this study?
11. Both parents must give permission.
12. One parent may consent if, with a note in the chart that only one parent was available.
13. If the child does not assent, both parents must give permission.
14. Dr. Belmont has had trouble recruiting participants into his trial of an experimental anti-inflammatory medication for osteoarthritis. He prints up fliers and distributes them in the clinic waiting room. The flier says: ‘Do you have arthritis? Take advantage of an exciting new treatment for arthritis, now available for the first time at this clinic. If you'd like to know more, contact Dr. Belmont at 123-4567. What are the problems with this approach?

 a. The flier doesn't mention that this is an experimental treatment

 b. Dr. Belmont should only recruit his own patients, not everyone in the clinic

 c. The IRB has not reviewed and approved this flier

 d. The consent form should be distributed with the flier

 e. A, and C.

1. An investigator received a notice from the drug company sponsoring his clinical trial that several adverse reactions were observed at other trial sites, and the safety committee for the trial requires suspension of the protocol. Which of these are appropriate steps for the investigator to take?

 a. Halt recruitment and inform the IRB of the suspension immediately;

 b. Halt recruitment and inform the IRB in the yearly Progress Report;

9. Carlos Balbo is planning to conduct a randomized trial in the Cook County Hospital Ambulatory Screening Clinic to test whether a fluoroquinolone antibiotic is better than placebo for acute bronchitis among 85 adults. For this study:

1. A Spanish language consent form will be requested, because Dr. Balbo’s recruitment of 10 or more can reasonably be expected to include a substantial number of non-English speaking Spanish speakers.
2. A Spanish-language consent form is recommended, as long as it is easy for the investigators to produce;
3. A short form consent inSpanish may be used along with the full English Consent.

10. Dr. John Jr. is conducting a randomized controlled study to test the efficacy of an investigational drug on patients with inoperable pancreatic cancer. It is hoped that the drug will extend the life of 25% of the subjects by more than 4 months. However, most patients in both arms die.

a. Dr. John Jr. must submit an “unexpected problem with increased risk report” to the IRB for each death.

b. Dr. John Jr. must complete an “unexpected problem with increased risk report” for each death, however he should file the report in the research record because the death is not “unexpected”

c. No report form is necessary because the deaths are tracked by the study sponsor.

11. The Scientific Quality Officer has inspected Dr. Racine's research site and found that signed consent forms for four subjects enrolled in this study are missing from Dr. Racine's file. When this is reported to the IRB, it directs that the study be suspended. What research activity can Dr. Racine carry out after suspension?

1. He may not enroll any new subjects, and must discontinue administration of the investigational drug, but can continue to gather research data from already enrolled subjects
2. He must halt all research activity including administration of the investigational therapy, unless the IRB agrees that subjects are likely suffer ill effects from abrupt termination of treatment.
3. He may not enroll any new subjects, but can continue to administer the investigational drug and follow already enrolled subjects.
4. He must ‘reconsent’ all his subjects as if this were a new protocol and then he can proceed with the study.

12. The consent form must be:

a. Signed by the person who informs the subject about the study and obtains the subject's informed consent.

b. Signed by the Principal Investigator.

 c. Signed by the participant.

 d. All of the above.

 e. A and C.

 13. Some of the patients Dr. Polk would like to enroll in his clinical trial are not cognitively aware enough to consent to research. None of these patients has a legally-appointed guardian, and many of them have no close relatives or friends who are willing to be involved in their care. For these patients, he asks a physician who is not involved in the research to sign the consent form on the patient's behalf. Is this an acceptable practice?

a. Yes, as long as Dr. Polk documents that no relative or close friend of the patient is reasonably available

b. Yes, as long as the physician is acquainted with the patient and involved in his/her care.

 c. No, this is not acceptable.

14. A new drug is being tested for a condition for which there are currently no approved drugs. During the course of the study, a previously investigational drug is approved by the FDA for this condition. The new drug does have negative side effects and is not advisable for all patients. The study has completed one year of participant recruitment; a second year of recruitment is planned with follow‑up scheduled to last for a total of five years. What action should the investigators take?

1. They must revise the consent form to reflect this new information;
2. They must inform the subjects previously recruited and repeat the consent process using the new form;
3. They must put patients on the newly approved drug.
4. They must include this in the progress report to the IRB which is submitted at least yearly;
5. A, B and D.
6. A, C and D.

15. The System policy governing financial interests in research was established because:

1. Institutional resources used for research must be monitored and fairly allocated
2. It is necessary to monitor the financial interests of all public employees.
3. The Sytem must assure the federal government that all subcontracts from grants are awarded fairly.
4. Personal financial interests might lead to biased research.

 16. Dr. Van Buren would like to use hospital and clinic records to study patients who are referred by the Emergency Department for follow up care in the outpatient clinics. Since he will follow the patient's records prospectively, he knows this study is not eligible for exemption from review. However, since the primary outcome measure is whether the patient kept the follow up appointment, Dr. Van Buren is also concerned that telling patients they are being studied will bias the study. He would like to request a waiver of consent for this study. To get permission to carry out this study without prior consent, he must convince the IRB of:

1. The study is no more risky than everyday life or a routine visit to the doctor.
2. The study can't practicably be carried out if he is required to get consent from the patients.
3. The patients whose records were followed will be told about the study after it's over.
4. The patients' rights and welfare won't be affected if they participate in this study.
5. All of the above
6. A-D plus he must request a waiver of HIPAA authorization.

17. The research projects in the System which are governed by federal regulations include:

 a. All human research projects

 b. Only those which are federally funded

 c. Only those which require a full IRB review

 d. Only those which will be published

18. Dr. Dearborn proposes to submit a case study for publication. She noticed, by chance that one of her patients on therapy for GERD no longer had problems with insomnia. The patient told her that she was not taking medication for insomnia and that she no longer had the need to. Dr. Dearborn looked through all of her patients on the GERD medication and found another who had been on medication for insomnia. She called this patient and the patient told her that she too had discovered she no longer need the sleeping pill. Which is the case?

a. Dr. Dearborn may publish the case report without IRB review because they do not fit the definition of research in 45CFR46 (systematic collection if data for a generalizable purpose). He is also free to submit it to provide a record.

b. Dr. Dearborn should submit the protocol, but it will be determined as research which is “exempt” from review.

c. If Dr. Dearborn wants to publish the case reports, she must submit a human subject research protocol for review like any other research project.

19. A new anti‑platelet drug is being tested against the standard therapy of aspirin in double blind randomized trial that was approved by the IRB. Because the new drug seems to produce uncomfortable side effects in about 15% of participants, the drug company sponsoring the study is willing to pay $25 at the conclusion of the study visit to each participant who is at least 80% compliant with therapy. Both the protocol and the payment have been approved by the IRB. Which of these statements is true?

1. Although they may be paid, the incentives may not be included in the advertisement
2. If the PI wishes to post recruitment fliers around the hospital and distribute them to other physicians, or change the consent, this plan must submitted to the IRB for review and approval.
3. The IRB has a responsibility to assess whether the incentives are potentially coercive.
4. Physicians may not recruit subjects from other physicians.

20. The consent form supplied by the drug company for the clinical trial of the experimental drug Miracle 2‑B includes the following sentence: ‘In the case of injury or illness resulting from this study, (name of facility) will provide emergency medical treatment. Medical care for such an injury or illness will be paid for by your regular payment method to (name of facility)’. For a consent to be used at a Bureau research site this sentence would be:

1. The minimum description of “compensation for injury” required in the consent form.
2. Unacceptable because compensation for lost wages is not offered.
3. Unacceptable because it asks the participant to sign away his or her legal rights.
4. Unacceptable because the drug company is not willing to pay for all the medical costs associated with the research.

21. Dr. Dogood at CCHHS wants to collaborate with Dr. Feelgood at another institution. They decide to gather health data on their respective patients and pool the findings for the statistical analysis. In order to share the patient information, which of the following are sufficient. (Mark ALL options which make sharing acceptable.)

1. Utilize an “Honest broker” who is not involved in the research who will de-identify the data before it is shared.
2. Get the signed authorization from the patient whose data are to be shared.
3. Be sure that only non-sensitive data (that does not include HIV status or mental health information) is included in the data set.
4. Send the data to be shared in a secure way (such as an encrypted attachment with a separate password).
5. Arrange a limited data set that does not include the 16 personal identifiers with a signed data use agreement.

22. Dr. Wacker Drive is doing a study on health access among poor and underserved minority patients. She creates a protocol offering case management services to patients at high risk of non‑adherence with treatment protocols. She will then follow them for five years. Her consent form contains the following statement concerning participant incentives:

*‘As compensation for your participation in this study, we will pay you $20 dollars for every study visit. There will be four visits per year, one per quarter, for five years. You will receive the $400 payment on your last visit, if you have completed all your visits.’*

 Is there a problem with this?

1. Yes: It is dangerous for participants to walk around with so much cash at the end of the year.
2. No: It clearly details the incentives to be given and the schedule by which they will be paid.
3. Yes: It is not legal for participants to be compensated for their participation in research projects.
4. Yes: It is coercive to withhold payments to enforce adherence to a visit schedule.

23. Which of the following is most important in the consent process?

a. The subject signing the consent form.

b. An information exchange between subject and investigator.

c. Maintenance of a ‘paper trail’ showing that the subject signed an approved consent form before being enrolled in a study.

d. Watching the subject read all the information in the consent form before signing it.

24. Dr. Sara Paretsky has applied to the IRB for approval of a protocol testing the safety of a new drug. The consent contains the following benefit statement, which is quoted in its entirety below:

‘Potential Benefit: Although it is unlikely that you will receive any direct medical benefit to your condition while you participate in this study, your participation will lead to the development of a new drug, which will save thousands of lives.’

 Is there a problem with this statement?

 a. Patients will not volunteer if they’re told they won’t benefit directly.

 b. Dr. Paretsky’s statement of direct benefit is ambiguous.

 c. Dr. Paretsky’s statement of long term benefit to science is too strong.

25. Dr. Terkle, an attending in emergency medicine, wants to conduct a survey in the emergency room and at several clinics to learn more about why some patients choose to go to a primary care clinic and others go directly to the emergency room for primary care. Which signatures must he obtain to approve his use of resources?

a. He must get the approval of the administrator responsible for the clinical area, Clinical division director (if there is one), and clinical department chair.

b. Although Fantus Clinic is located on the hospital campus, it is an Ambulatory Community Health Network (ACHN) facility and the responsible administrator for all clinics at Fantus and JSH including specialty clinics and *each other* site must sign off.

c. Research in the ambulatory network must have the approval of the ACHN leadership.

 d. All of the above

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