Research Gaming

(with some holiday fun thrown in)

SCORE

December 8, 2016

What's on Deck?

- OHSP-QI Crossword Puzzle
  - 2015 OHSP Q3 Newsletter

responsible

39) The individual response for implementing the University's HRPP (and therefore, ultimately the OHSP-QI program).

What's on Deck?

- Quasi-Jeopardy
  - No answers in the form of questions
  - Question format varies
  - Numerical values hold no meaning
  - Poll Everywhere & holiday questions scattered among each category

Investigator Responsibilities	Truths & Lies	Drugs & Devices	IRB	Grab Bag
10	10	10	10	10
20	20	20	20	20
30	30	30	30	30
40	40	40	40	40
50	50	50	50	50

Truths & Lies Category

- 2 true statements + 1 false statement
- Identify the FALSE statement
- Example:

1) The sky is blue.
2) 2 + 2 = 4
3) Kelly is secretly married to Ryan Reynolds.

Investigator Responsibilities

Question

When a subject reports an adverse event, who is responsible for determining the event's relatedness to participation?

Answer

Principal Investigator
(or appropriately delegated co/sub-investigator)

Question

Answer

Winter Wonderland
Tony Bennett & Lady Gaga

Question

You are initiating a new study sponsored by Pfizer. One of your sub-investigators receives ~$4000/year from Pfizer for consulting. As this investigator is already involved in another Pfizer-sponsored study and has a COI management plan in place, no additional COI reporting is required for the new study.

True or False?

Answer

False

Answer

- Scientific merit
  - Justified & relevant? Why?
  - Design aligns with objectives?
- Ethical design
  - Belmont Report principles respected?
- Study protocol
  - Protocol procedures vs. routine care?
  - Length of intervention?
  - Number/types of study procedures?
  - Dosing rationale? Endpoints?
  - Enrollment expectations vs. eligible subjects?
  - Competing trials?
  - Space & equipment?
- Staffing & time commitment
- Budget

Question

What's wrong with this picture?

Please mark an X in the boxes below to indicate if you want to donate your leftover tissue for future research (as described above on page 4).

☐ Yes, I give my permission to store leftover tissue for future research.
☐ No, I do not want my leftover tissue stored for future research.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

1/16/2014
Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read
provide the subject with a signed copy of this consent form. An
the research was given and questions from the subject were so
answered to the subject's satisfaction. In my judgment, the sub
demonstrated comprehension of the information. I have given t
adequate opportunity to read the consent before signing.

Kelly Unsworth, Study Coordinator
Name and Title (Print)

Signature of Person Obtaining Consent

1/18/2014
Date

RSRB# 54321
11/1/2013

Page 5 of 5

RSRB-University of Rochester-Approval
RSRB No. 54321
Expires January 7, 2014
- mac 11/4/13 -

RSRB-University of Rochester-Approval
RSRB No. 54321
Expires January 7, 2014
- mac 11/4/13 -

Answer

- Consent form expiration date has passed
- Subject & POC signature dates differ
- Checkbox options are incomplete
- Handwriting (dates) looks similar

Truths & Lies

Answer

1) All expedited and full board research must be reviewed by the IRB at least annually.

2) Continuing non-compliance may or may not result in increased risk to subjects.

3) The Institutional Official can approve research disapproved by the RSRB.

Question

1) Certificates of Confidentiality (COC) prevent voluntary disclosures and provide permanent protection of information collected about the research subjects while the certificate is in effect.

2) Research events that are not deemed unanticipated, serious and related or do not involve increased risk to subjects or others should be reported to the RSRB at the time of continuing review.

3) Study teams may continue to work with a dataset after a study has been closed, as long as identifiers have been removed from the dataset.

Answer

1) Certificates of Confidentiality (COC) prevent voluntary disclosures and provide permanent protection of information collected about the research subjects while the certificate is in effect.
   - COCs protect against compulsory legal demands (e.g., court orders and subpoenas) BUT not protect against voluntary disclosure
   - Protection is permanent

2) Research events that are not deemed unanticipated, serious and related or do not involve increased risk to subjects or others should be reported to the RSRB at the time of continuing review.

3) Study teams may continue to work with a dataset after a study has been closed, as long as identifiers have been removed from the dataset.

Question

Fill in the Blank:

"The best way to spread Christmas Cheer, is _____."

- Buddy the Elf

Answer

Fill in the Blank:

"The best way to spread Christmas Cheer, is singing loud for all to hear."

- Buddy the Elf

Question

1) A final progress report must be submitted to the RSRB once a study is complete; allowing a study to lapse is insufficient.

2) Determinations regarding serious and continuing non-compliance can only be made by the convened board, regardless of the risk level of the research.

3) The definition of 'minimal risk' is the same for all types of research, regardless of the procedures involved or the population being studied.

Answer

1) A final progress report must be submitted to the RSRB once a study is complete; allowing a study to lapse is insufficient.

2) Determinations regarding serious and continuing non-compliance can only be made by the convened board, regardless of the risk level of the research.

3) The definition of 'minimal risk' is the same for all types of research, regardless of the procedures involved or the population being studied.
   - 45CFR46.303 (Subpart C – Prisoners): Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination *of healthy persons*

Question

1) A dataset coded with a subject identification number is considered de-identified as long as the source linking the subject's identity and the number is stored separately.

2) An important factor in determining if a research event is unanticipated is whether the event is identified as a risk in the study protocol and investigator's brochure.

3) UR officials with supervisory responsibilities (e.g., Institutional Official, Department Chair, Dean or President) can disapprove research approved by the RSRB.

Answer

1) A dataset coded with a subject identification number is considered de-identified as long as the source linking the subject's identity and the number is stored separately.

2) An important factor in determining if a research event is unanticipated is whether the event is identified as a risk in the study protocol and investigator's brochure.

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Drugs & Devices

Question

Who is responsible for justifying whether an investigational device is non-significant risk?

Answer

Sponsor
(Principal Investigator)

Answer

When does an IND go into effect after the FDA receives the application (provided no clinical holds)?

a) 30 days
b) 90 days
c) Once the sponsor submits all 1572s from the study sites
d) When the FDA provides written notification of approval

Question

The dosing for an investigational drug intervention is 2 tablets, 2 times a day. Subjects return for study visits every 18-21 days. How many tablets should be dispensed to subjects at each study visit?

Answer

84 tablets
(4 tablets daily x 21 days = 84 tablets)

Question

LATKES AND SUFGANIOT

Hint: Traditional Festival of Lights Fare

Answer

Latkes and Sufganiot

Question

Investigators are responsible for including a plan for the control of investigational drugs/devices in the study protocol. What types of procedures does this plan typically include?

Answer

- Receipt
- Handling & Storage
- Dispensing
- Subject Accountability
- Disposition

Institutional Review Board

Question

S W A H I L I

Hint: Kwanzaa Greeting

Answer

Swahili

Question

True or False?

Approve a study with stipulations versus tabling a study is a regulatory determination that does not affect the review process; in either case changes to the research need to be made by the study team.

Answer

False

Question

What types of events must the RSRB promptly report to OHRP and the FDA?

Answer

1) Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)

2) Serious or continuing non-compliance

3) Suspension or termination of approval

Question

What's missing?

1) Risks minimized
2) Risks are reasonable in relation to anticipated benefits
3) _____
4) Informed consent will be sought/obtained
5) Informed consent will be documented
6) Adequate provisions for monitoring the data to ensure subject safety
7) _____
8) Additional safeguards for vulnerable populations

Answer

What's missing?

1) Risks minimized
2) Risks are reasonable in relation to anticipated benefits
3) Selection of subjects is equitable
4) Informed consent will be sought/obtained
5) Informed consent will be documented
6) Adequate provisions for monitoring the data to ensure subject safety
7) Privacy protected & confidentiality maintained
8) Additional safeguards for vulnerable populations

Answer

1) Waiver of parental permission requested for research involving children

2) Research involving adults with decisional impairments approved under 'Category C' (minor increase over minimal) that includes a subject population that may not have the capacity to designate a research proxy

Grab Bag

Question

Who is responsible for conducting scientific review of human subject research protocols (inclusive of scientific merit, risk identification and management, and investigator qualifications and resources)?

Answer

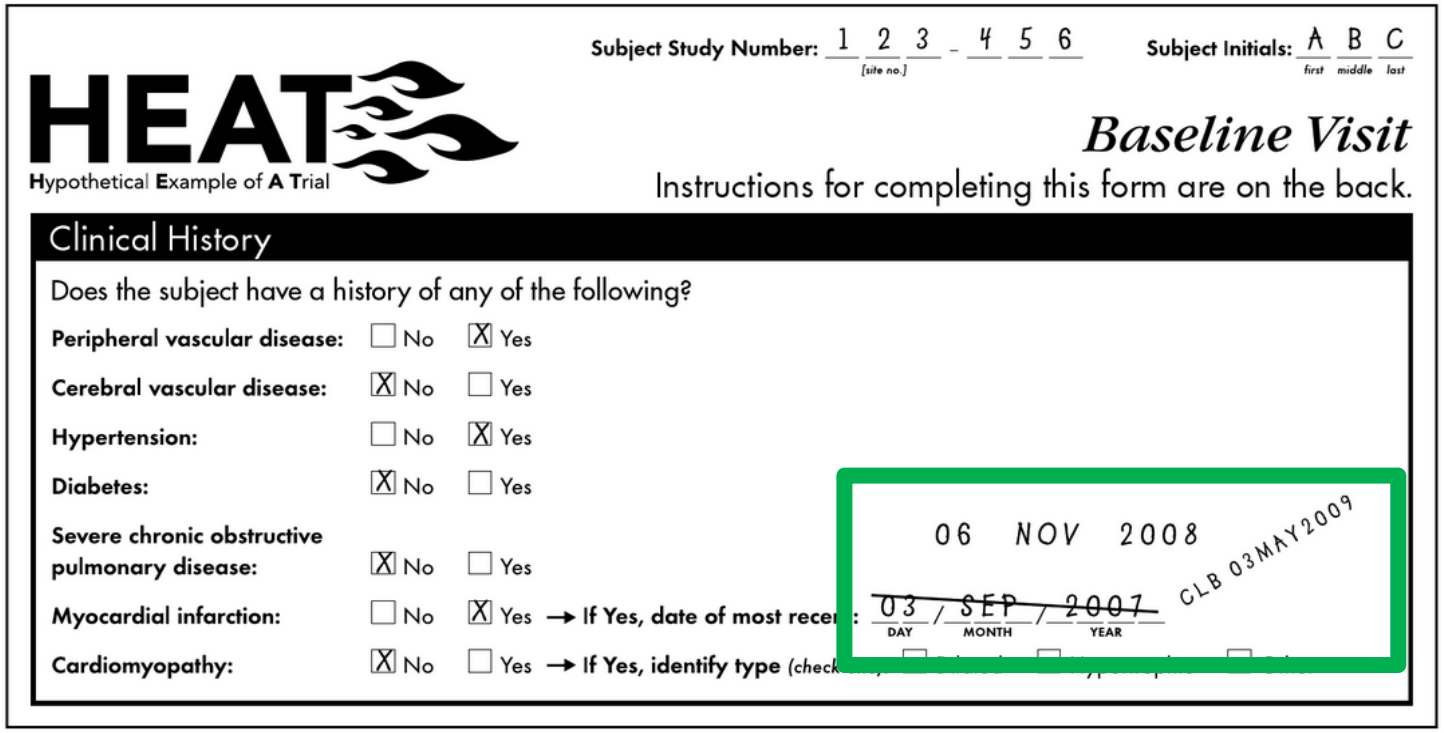
Scientific Reviewer(s) designated by the leadership of the Principal Investigator's Department, Center or School

Question

What is the correct method for changing information documented on a consent form, case report form or any other study document?

Answer

GCP 4.9.3: "Any change or correction…should be dated, initialed and explained (if necessary) and should not obscure the original entry (i.e., an audit trial should be maintained)"



Subject Study Number: 1 2 3 - 4 5 6 [site no.] Subject Initials: A B C first middle last

HEAT
Hypothetical Example of A Trial

Baseline Visit

Instructions for completing this form are on the back.

Clinical History

Does the subject have a history of any of the following?

Peripheral vascular disease:	☐ No	☒ Yes
Cerebral vascular disease:	☒ No	☐ Yes
Hypertension:	☐ No	☒ Yes
Diabetes:	☒ No	☐ Yes
Severe chronic obstructive pulmonary disease:	☒ No	☐ Yes
Myocardial infarction:	☐ No	☒ Yes → **If Yes, date of most recen:** 03 / SEP / 2007 (DAY / MONTH / YEAR)
Cardiomyopathy:	☒ No	☐ Yes → **If Yes, identify type** (check

06 NOV 2008 CLB 03MAY2009

From: Liu, M. & Davis, K. (2009). *Clinical Trials Manual from the Duke Clinical Research Institution: Lessons from a Horse Named Jim*. Hoboken, NJ: Wiley-Blackwell.

Answer

- Date
- Department letterhead
- IRB/Protocol #
- Description of the problem/error
- Root cause of problem/error
- Correction &/or preventative action
- Resolution
- Signature of individual writing the Note to File

Question

After conducting a focus group at an off-site location, the digital recorder you used to record the focus group goes missing. Participants were instructed to use pseudonyms during the recorded portion of the focus group. How should this be reported to the RSRB?

a) Within 5 days as a local serious adverse event
b) Within 10 days as a UPIRTSO
c) At the time of continuing review
d) It doesn't need to be reported

Answer

After conducting a focus group at an off-site location, the digital recorder you used to record the focus group goes missing. Participants were instructed to use pseudonyms during the recorded portion of the focus group. How should this be reported to the RSRB?

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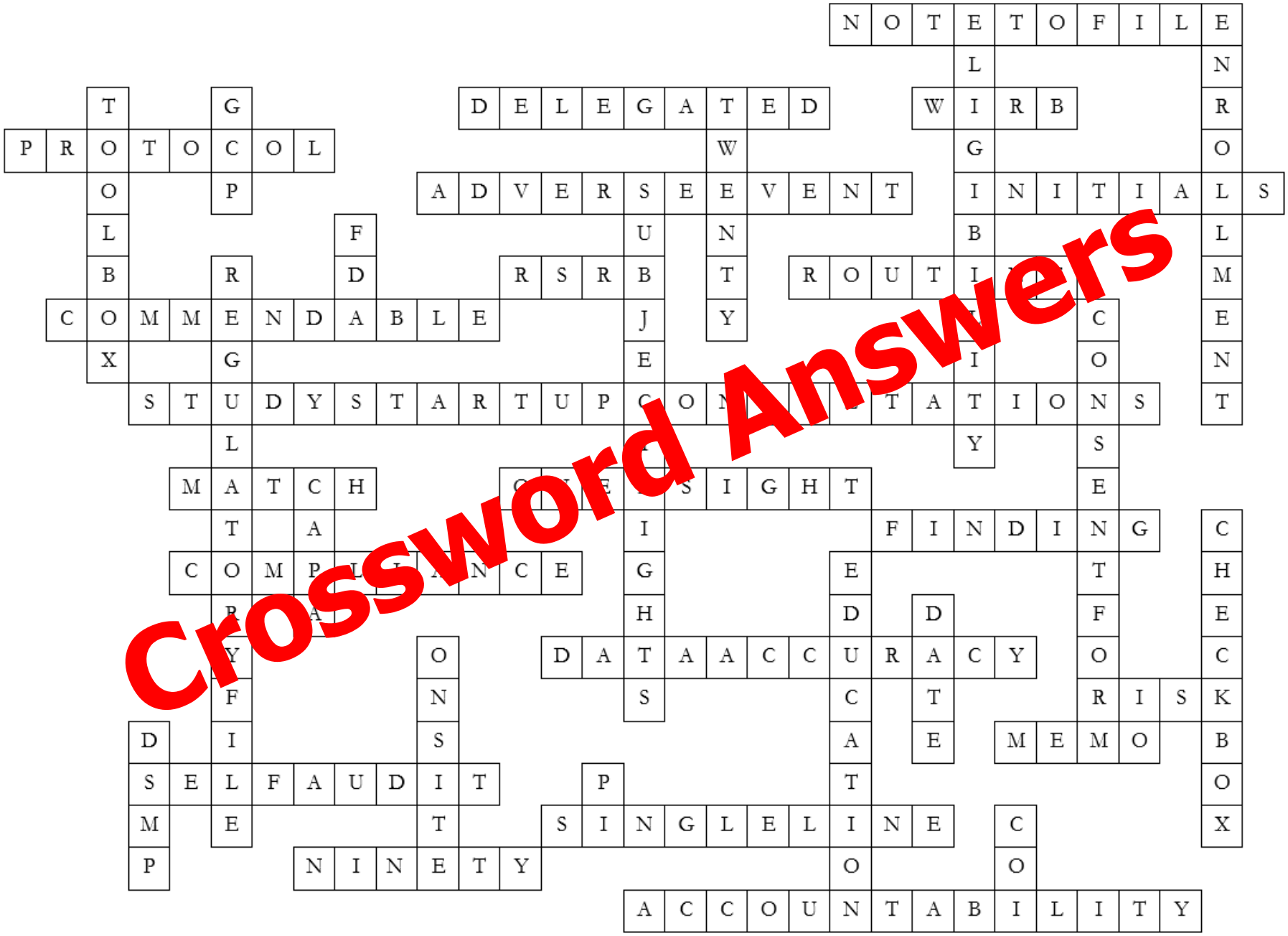
Question

Answer

Baby, It's Cold Outside
James Taylor & Natalie Cole


Crossword Answers


Happy Holidays