



Clinical Research Jeopardy – Test Your Knowledge

Host

Susmita Jain, MS

Research QI, Compliance and Education Specialist

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JEOPARDY

Welcome Everyone!

Thank you to those who registered to participate as a game contestant. Everyone else can just relax and enjoy the game show and learn!

TEAM INTRODUCTION

1. NONSTOP NINJAS
2. TASKFORCE TITANS
3. SYNERGY SYNDICATES
4. WORKS WIZARDS

GAME RULES

- Three-round trivia game – **JEOPARDY, DOUBLE JEOPARDY and FINAL JEOPARDY**
- Before the beginning of each round, I will explain the rules of that round.
- Questions are worded as answers and answers must be worded in the form of a question, beginning with “what is” or “who are” for example.
- Lauren Thomas will be tracking the game timer and score.
- **Everyone will be muted!** Use the **RAISE HAND ICON** to talk. We will unmute the person once his/her turn comes to speak. Before you speak, please mention your name.
- **REMEMBER - NO PROMPTING OR TYPING THE ANSWER IN THE CHAT BOX UNLESS ASKED.**

ROUND 1 – JEOPARDY RULES

- Anyone on the team can attempt and answer the question for the team. We will rotate calling on individuals on the team, but only if they raise their hand.
- To begin, I will randomly pick the team and ask who would like to go first? The person who raises the hand first from that team will prompt their name and pick the question category and related dollar amount.
- The selected person will get 10 seconds to answer.
- REMEMBER, The team will earn the points for the correct answer within the time limit and lose points for no answer or a wrong answer.
- In case of no answer or wrong answer, I will reveal the answer and will move to the next team to choose the next question.

RESEARCH CONDUCT	CLINICAL RESEARCH HISTORY	ETHICS AND REGULATIONS	MISCELLANEOUS	WHO AM I ?	ACRONYMS
\$200	\$200	\$200	\$200	\$200	\$200
\$400	\$400	\$400	\$400	\$400	\$400
\$600	\$600	\$600	\$600	\$600	\$600
\$800	\$800	\$800	\$800	\$800	\$800
\$1000	\$1000	\$1000	\$1000	\$1000	\$1000

NONSTOP NINJAS	TASKFORCE TITANS	SYNERGY SYNDICATES	WORK WIZARDS
Jocelyn Contesti	Kathy Reichel	Siddharth Gandhi	Paula Strussione
Jill George	Melissa Bukowski	Valentyna Onishchuk	Joan Morey
Tanya Gardner Mosley	Michele Lowe	Sarah LaMontagne	Qura Abid
Kelley Wilson	Paige Puchalski	Denise Antonishen	Swan Atty
Lisa Zajac	Camille Howey	Emily Paschell	Anita Crosena
	James Shock		





RESEARCH CONDUCT - \$200

THE COMPREHENSIVE DOCUMENT THAT OUTLINES THE
ESSENTIAL DETAILS FOR CONDUCTING A CLINICAL TRIAL

10 sec
time up!

WHAT IS THE PROTOCOL?

← BACK TO PANEL



RESEARCH CONDUCT - \$400

ANOTHER WAY TO SAY “LIKE A FLIP OF A COIN”

10 sec
time up!

WHAT IS RANDOMIZATION?

← BACK TO PANEL



RESEARCH CONDUCT - \$600

THIS IS A SYSTEM USED BY THE SPONSOR AND OR INVESTIGATOR
TO RECORD RESEARCH SUBJECTS DATA ELECTRONICALLY

10 sec
time up!

WHAT IS ELECTRONIC DATA CAPTURE (EDC) SYSTEM?

← BACK TO PANEL



RESEARCH CONDUCT - \$800

THE CONSENT FORM RESEARCH RELATED INJURY LANGUAGE SHOULD MATCH THE SAME LANGUAGE IN THIS LEGAL CONTRACT

10 sec
time up!

WHAT IS CLINICAL TRIAL AGREEMENT?

← BACK TO PANEL



RESEARCH CONDUCT - \$1000

A CHARACTERISTIC THAT DISQUALIFIES A POTENTIAL PARTICIPANT
FROM PARTICIPATING IN A PARTICULAR CLINICAL TRIAL

10 sec
time up!

WHAT IS EXCLUSION CRITERIA?

← BACK TO PANEL



CLINICAL RESEARCH HISTORY - \$200

THIS REPORT DESCRIBES THE FUNDAMENTAL ETHICAL PRINCIPLES OF RESPECT, BENEFICENCE, AND JUSTICE AS KEY COMPONENTS OF CLINICAL RESEARCH ON HUMAN SUBJECTS

10 sec
time up!

WHAT IS BELMONT REPORT?

← BACK TO PANEL



CLINICAL RESEARCH HISTORY - \$400

THE FIRST SET OF 10 ETHICAL PRINCIPLES THAT GOVERNED
HUMAN EXPERIMENTATION

10 sec
time up!

WHAT IS THE NUREMBERG CODE?

← BACK TO PANEL



CLINICAL RESEARCH HISTORY - \$600

THE DRUG WAS PRESCRIBED TO PREGNANT WOMAN IN THE
1950s AND 1960s TO TREAT MORNING SICKNESS.
UNFORTUNATELY, IT WAS LATER DISCOVERED THAT IT CAUSED
SEVERE BIRTH DEFECTS IN BABIES

10 sec
time up!

WHAT IS THALIDOMIDE TRAGEDY?



← BACK TO PANEL



CLINICAL RESEARCH HISTORY - \$800

IN 1938 THE SULFAONAMIDE DRUG TRAGEDY LED TO THIS ACT

10 sec
time up!

WHAT IS FEDERAL FOOD DRUG AND COSMETICS ACT?

← BACK TO PANEL



CLINICAL RESEARCH HISTORY - \$1000

THIS SCOTTISH NAVAL SURGEON CONDUCTED THE FAMOUS 1747 PROSPECTIVE CONTROLLED CLINICAL TRIAL ON SCURVY IN SAILORS

10 sec
time up!

WHO IS DR. JAMES LIND?

← BACK TO PANEL



ETHICS & REGULATIONS - \$200

MCLAREN HEALTH CARE'S HUMAN RESEARCH PROTECTION PROGRAM IS ACCREDITED BY THIS AGENCY

10 sec
time up!

WHAT IS ASSOCIATION FOR ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS (AAHRPP)?

← BACK TO PANEL



ETHICS & REGULATIONS - \$400

STUDIES USING PROTECTED HEALTH INFORMATION (PHI)
WITHOUT SUBJECT PERMISSION NEED THIS

10 sec
time up!

WHAT IS WAIVER OF HIPAA AUTHORIZATION?

← BACK TO PANEL



ETHICS & REGULATIONS - \$600

**THIS REPORT IS ISSUED BY THE FDA AFTER AN INSPECTION
OBSERVED CONDITIONS DEEMED TO BE OBJECTIONABLE**

10 sec
time up!

WHAT IS FORM 483?

← BACK TO PANEL



ETHICS & REGULATIONS- \$800

AN INTERNATIONAL ETHICAL AND SCIENTIFIC QUALITY
STANDARD FOR DESIGNING, CONDUCTING, RECORDING AND
REPORTING TRIALS

10 sec
time up!

WHAT IS ICH GCP?

← BACK TO PANEL



ETHICS & REGULATIONS - \$1000

ACCORDING TO THIS PRINCIPLE, RESEARCH SUBJECTS SHOULD BE SELECTED FAIRLY AND THAT THE RISK AND BENEFITS OF THE RESEARCH SHOULD BE DISTRIBUTED EQUITABLY AMONG DIFFERENT POPULATIONS

10 sec
time up!

WHAT IS THE PRINCIPLE OF JUSTICE?

← BACK TO PANEL



MISCELLANEOUS - \$200

AN EVENT THAT RESULTS IN DEATH, IS LIFE THREATENING, OR
HAS OTHER SERIOUS CONSEQUENCES

10 sec
time up!

WHAT IS SERIOUS ADVERSE EVENT?

← BACK TO PANEL



MISCELLANEOUS - \$400

THIS MEANS ADHERENCE TO ALL STUDY RELATED POLICIES,
REGULATIONS AND LAWS

10 sec
time up!

WHAT IS COMPLIANCE?

← BACK TO PANEL



MISCELLANEOUS - \$600

AN INVESTIGATOR SIGNS THIS FORM TO ENSURE COMPLIANCE
WITH THE FDA CODE OF FEDERAL REGULATIONS FOR THE
CLINICAL TRIAL

10 sec
time up!

WHAT IS FORM 1572?

← BACK TO PANEL



MISCELLANEOUS - \$800

A PERSON RESPONSIBLE FOR SHIPPING DANGEROUS GOODS TRANSPORTED BY A PUBLIC CARRIER MUST FOLLOW SPECIFIC REGULATIONS AND MUST HAVE PROOF OF THIS TRAINING

10 sec
time up!

WHAT IS IATA TRAINING?

← BACK TO PANEL



MISCELLANEOUS - \$1000

A REVIEW THAT ASSESSES THE PRACTICALITY OF A PROPOSED RESEARCH STUDY TO ENSURE IT CAN BE COMPLETED SUCCESSFULLY

10 sec
time up!

WHAT IS PROTOCOL FEASIBILITY REVIEW?

← BACK TO PANEL



WHO AM I? · \$200

AN INDIVIDUAL, JUDICIAL BODY OR OTHER BODY AUTHORIZED
UNDER APPLICABLE LAW TO CONSENT ON BEHALF OF A
PROSPECTIVE SUBJECT

10 sec
time up!

WHO IS A LEGALLY AUTHORIZED REPRESENTATIVE OR LAR?

← BACK TO PANEL



WHO AM I? - \$400

THIS GROUP ENSURES THAT RISKS ARE REDUCED AND ARE
OUTWEIGHED BY THE POTENTIAL BENEFITS OF THE STUDY FOR
SUBJECTS

10 sec
time up!

WHO IS AN IRB?

← BACK TO PANEL



WHO AM I? - \$600

A PERSON OR ORGANIZATION CONTRACTED BY THE SPONSOR
TO PERFORM ONE OR MORE OF A SPONSOR'S STUDY RELATED
DUTIES AND FUNCTIONS

10 sec
time up!

WHO IS THE CONTRACT RESEARCH ORGANIZATION OR CRO?

← BACK TO PANEL



WHO AM I? - \$800

MCLAREN HEALTH CARE'S INSTITUTIONAL OFFICIAL



10 sec
time up!

WHO IS DR. JUSTIN KLAMERUS?

← BACK TO PANEL



WHO AM I? - \$1000

AN AFRICAN AMERICAN WOMAN WHOSE CANCER CELLS WERE USED WITHOUT CONSENT AND ARE THE SOURCE OF THE HELA CELL LINE, THE FIRST IMMORTALIZED HUMAN CELL LINE AND ONE OF THE MOST IMPORTANT CELL LINES IN MEDICAL RESEARCH

10 sec
time up!

WHO IS HENRIETTA LACKS?

← BACK TO PANEL



ACRONYMS - \$200

CAPA

10 sec
time up!

**WHAT IS THE CORRECTIVE ACTION - PREVENTIVE
ACTION?**

← BACK TO PANEL



ACRONYMS · \$400

ePRO

10 sec
time up!

WHAT IS THE ELECTRONIC PATIENT REPORTED OUTCOMES?

← BACK TO PANEL



ACRONYMS · \$600

DSMB

10 sec
time up!

WHAT IS DATA SAFETY MONITORING BOARD?

← BACK TO PANEL



ACRONYMS · \$800

SUSAR

10 sec
time up!

**WHAT IS SUSPECTED UNEXPECTED SERIOUS ADVERSE
REACTION?**

← BACK TO PANEL



ACRONYMS · \$1000

ALCOA-C

10 sec
time up!

WHAT IS ATTRIBUTABLE, LEGIBLE, CONTEMPORANEOUS,
ORIGINAL, ACCURATE, AND COMPLETE?

← BACK TO PANEL

SCORE BOARD



DOUBLE JEOPARDY

ROUND 2 – DOUBLE JEOPARDY RULES

START

- This round has 3 categories. **You will earn double the related dollar amounts for each correct answer and lose double points for each wrong answer:**
- To begin this round, I will start with the **team that scored lowest** and ask who would like to go. The person who raises the hand first from that team will pick the question category and related dollar amount.
- The selected person will get 10 seconds to answer. At the end of 10 seconds if the chosen person does not know the answer and someone else from that team would like to prompt the answer, that will be acceptable.
- **REMEMBER - This time the answer must be worded in the form of a question. If not, then you lose the points.**
- In case of no answer or wrong answer, I will reveal the answer and will move to the next team to choose the next question and related dollar amount.
- Play proceeds the same as in Round 1, until all the questions have been played or as time permits.

SCORE BOARD

ROUND 2 - DOUBLE JEOPARDY

NEXT ROUND

TYPE OF RESEARCH		"D" FOR DOCUMENT		GIVE ME AN EXAMPLE	
\$200		\$200		\$200	
\$400		\$400		\$400	
\$600		\$600		\$600	
\$800		\$800		\$800	
\$1000		\$1000		\$1000	

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DOUBLE JEOPARDY – TYPE OF RESEARCH · \$200

**THIS RESEARCH OCCURS FIRST IN THE LAB BEFORE CONDUCTING
HUMAN RESEARCH**

10 sec
time up!

WHAT IS PRECLINICAL RESEARCH?

BACK TO PANEL



DOUBLE JEOPARDY - TYPE OF RESEARCH - \$400

A CLINICAL TRIAL IN WHICH PARTICIPANTS AND INVESTIGATOR ARE AWARE OF THE TREATMENT RECEIVED

10 sec
time up!

WHAT IS OPEN LABEL STUDY?

[BACK TO PANEL](#)



DOUBLE JEOPARDY – TYPE OF RESEARCH · \$600

THIS TYPE OF RESEARCH INVOLVES LOOKING AT PAST
MEDICAL RECORDS

10 sec
time up!

WHAT IS RETROSPECTIVE CHART REVIEW?

[BACK TO PANEL](#)



DOUBLE JEOPARDY – TYPE OF RESEARCH · \$800

A TRIAL THAT EXAMINES THE SAFETY AND EFFECTIVENESS OF
A DRUG OR TREATMENT AFTER IT HAS BEEN APPROVED BY
THE FDA AND IS AVAILABLE TO THE PUBLIC

10 sec
time up!

WHAT IS PHASE 4 CLINICAL TRIAL?

[BACK TO PANEL](#)



DOUBLE JEOPARDY – TYPE OF RESEARCH - \$1000

THE STUDY OF TIME COURSE OF DRUG ABSORPTION,
DISTRIBUTION, METABOLISM, AND EXCRETION AFTER ITS
ADMINISTRATED TO THE BODY

10 sec
time up!

WHAT IS PHARMACOKINETICS?

[BACK TO PANEL](#)



DAILY DOUBLE - "D" FOR DOCUMENT - \$200

ORIGINAL, PRIMARY RECORDS OF THE EVENTS OR DATA

10 sec
time up!

WHAT ARE SOURCE DOCUMENTS?

[BACK TO PANEL](#)



DOUBLE JEOPARDY - "D" FOR DOCUMENT - \$400

A DOCUMENT THAT REQUIRES INVESTIGATORS TO DISCLOSE
THEIR FINANCIAL INTERESTS, COMPENSATION, AND
ARRANGEMENTS TO SPONSOR/FDA/IRB FOR THAT CLINICAL
TRIAL

10 sec
time up!

WHAT IS FINANCIAL DISCLOSURE?

[BACK TO PANEL](#)



DOUBLE JEOPARDY - "D" FOR DOCUMENT - \$600

THIS LOG CAPTURES THE ROLES AND RESPONSIBILITIES OF EACH OF THE MEMBER OF THE RESEARCH TEAM FOR A GIVEN STUDY

10 sec
time up!

WHAT IS THE DELEGATION OF AUTHORITY (DOA) LOG?

[BACK TO PANEL](#)



DOUBLE JEOPARDY - "D" FOR DOCUMENT - \$800

THIS DOCUMENT COMPILES DATA RELEVANT TO STUDIES OF THE INVESTIGATIONAL PRODUCT IN HUMAN SUBJECTS GATHERED DURING PRECLINICAL AND OTHER CLINICAL TRIALS.

10 sec
time up!

WHAT IS THE INVESTIGATOR BROCHURE?

[BACK TO PANEL](#)



DOUBLE JEOPARDY - "D" FOR DOCUMENT - \$1000

THE COMMON RULE IS LOCATED UNDER THIS HHS REGULATION

10 sec
time up!

WHAT IS 45CFR46?

BACK TO PANEL



DOUBLE JEOPARDY - GIVE ME AN EXAMPLE - \$200

**RESEARCH COORDINATOR PERFORMED THE STUDY VISIT 1 DAY
OUT OF WINDOW. THIS IS AN EXAMPLE OF**

10 sec
time up!

WHAT IS PROTOCOL DEVIATION?

BACK TO PANEL



DOUBLE JEOPARDY - GIVE ME EXAMPLE - \$400

A SUBJECT DEVELOPED HIVES IMMEDIATELY AFTER THE STUDY
DRUG ADMINISTRATION. THIS IS THE EXAMPLE OF

10 sec
time up!

WHAT IS AN ADVERSE EVENT?

[BACK TO PANEL](#)



DOUBLE JEOPARDY - GIVE ME EXAMPLE - \$600

RESEARCHERS WILL BE CONDUCTING STUDY ON SAFETY OF
NEW VACCINE IN CHILDREN. THIS SUBJECT POPULATION IS AN
EXAMPLE OF

10 sec
time up!

WHAT IS A VULNERABLE POPULATION?

[BACK TO PANEL](#)



DOUBLE JEOPARDY - GIVE ME EXAMPLE - \$800

RESEARCH COORDINATOR SHARED THE RESEARCH SUBJECT'S
PERSONAL INFORMATION WITH HIS FRIEND. THIS IS AN
EXAMPLE OF

10 sec
time up!

WHAT IS HIPAA VIOLATION?

[BACK TO PANEL](#)



DOUBLE JEOPARDY - GIVE ME EXAMPLE - \$1000

WHEN OUTSIDE INTERESTS COULD UNDULY INFLUENCE
PROFESSIONAL JUDGEMENT OF AN INDIVIDUAL INVOLVED IN A
RESEARCH PROJECT, THIS IS AN EXAMPLE OF

10 sec
time up!

WHAT IS CONFLICT OF INTEREST?

[BACK TO PANEL](#)

SCORE BOARD



FINAL JEOPARDY

- This round has ONLY ONE QUESTION.
- To begin this round, I will DISPLAY THE CATEGORY to all the teams that scored at least 0.
- The team will be put in a breakout room for 2 minutes to discuss and decide their wager amount and select the person who will type the answer in the chat box. Depending on their confidence in answering the category, they can wage up to their entire score.
- After 2 minutes, all the teams will get back to the main game room and I will note down their wager amount and name of the person who will type the answer in chat box.
- I will display the question and put the team back to the breakout room for 2 minutes to decide the answer
- At the end of 2 minutes, the team will come back with the answer and I will ask the team representative to type the answer in chat box within 10 seconds.
- If the answer is correct, the team will earn the wager amount which will be added in their score
- If the answer is wrong, the team will lose the wager amount which will be deducted from their score
- Once the FINAL JEOPARDY SCORES ARE CALCULATED, The team with the highest score will win the game.





FINAL JEOPARDY

CATEGORY - ARRANGE ME IN ORDER PLEASE

CATEGORY - ARRANGE ME IN ORDER PLEASE



Research Subject # 236 is participating in a double-blind clinical drug trial. On day 5 of the study drug treatment, he went into cardiac arrest right after the administration of the study drug at the research clinic. The research nurse immediately initiated clinic emergency procedures.

The treating hospital physician requested to know exactly what study drug was given to the patient to provide further medical care.

The study team is working to take action in response to this SAE event. Please help them by arranging the action items in order.

1. PI will break the blind to provide the necessary information to the treating physician
2. The research nurse will submit the SAE report with available information to the study sponsor
3. The research nurse will report the SAE event to the PI
4. The research nurse will report the SAE event to the IRB

RESPONSE



1. The research nurse will report the SAE event to the PI
2. PI will break the blind to provide the necessary information to the treating physician
3. The research nurse will submit the SAE report with available information to the study sponsor
4. The research nurse will report the SAE event to the IRB

WINNER

SCORE BOARD

WINNER!