# BRIDGE Patient to Investigator Training
# Overall Assessment

## Module 1 What it Means to Be a Patient/Caregiver Investigator

**Match the following words to the definition that makes the most sense:**

| | |
|---|---|
| **1._____ Research Advocate** | a. Provide advice, often limited, to researchers. These individuals have a narrow role—researchers approach them to review a specific part of the research—***they do not have a voice at all phases of the research study and they are not a member of the research team.*** |
| **2._____ Patient/Caregiver Investigator** | b. Promote, often to other patients and their families, the need to participate—as "participants" in research. They have often been a research participant and promote others to become research participants as well. ***They are not involved in developing or actually doing the research studies.*** |
| **3._____ Patient Advisor** | c. They are **participating members** of research teams that are **actively involved** throughout all steps of the research process |

**4. As a patient/caregiver investigator, you will participate in all phases of the research study.**

a. False

b. True

**5. What will you NOT do as a patient/caregiver investigator?** *(choose the one answer that makes the most sense.)*

a. Join study team calls

b. Be expected to know how to design a research study

c. Review study materials

d. Share your perspective

## Module 2: Building Confidence

**6. Which of the following statements is NOT true about patient/caregiver investigators?**

a. Soft skills are the traits that make you a good team member, such as etiquette, communication, listening and getting along with other people.

b. Telling your story is a way to convey your point/perspective and can be very helpful to your other research team members.

c. As a participant on a research team, you can remind other study team members to use plain language – avoid jargon (acronyms, technical terms).

d. While participating on a research team, avoid asking questions or offering your opinion.

e. You are teaching them (your other team members) just as much as you are learning from everyone.

**7. Which of the following is NOT an example of "experiential knowledge":**

a. Knowledge/wisdom gained through life experiences

b. Formal training

c. Understanding COPD better than individuals who have not had the disease or who have not cared for someone with the disease.

**8. Which question below is an example of an appropriate question to ask the study team before starting a study?**

a. How much of my time will this take?

b. Will I receive payment for my time?

c. Can you send me a plain language summary of the study?

d. What do you hope I will contribute to the team?

e. All of the above.

## Module 3: Types of Research

**9. This COPD Foundation Training is focused on which type of research (choose one answer below):**

a. Animal—studying how treatments work in animals

b. Molecular—studying disease at the cellular level

c. Human Participants—research that deals with patients, patient information or care given to patients

d. All of the above

**10. Which of the following statements is NOT TRUE for Observational studies**? (choose one)

a. Researchers gather information about something that has already happened.

b. Nothing is changed—there is no intervention.

c. Researchers make a change with one group of patients and observe how the change affected the patients.

d. The research team observes, gathers, measures, records and analyzes information and makes a conclusion.

**11. Which of the following statements is NOT TRUE for Experimental studies (choose one)**

a. The research team makes a change with one group of patients and then observes how this change affected the patient.

b. The "changed" or *intervention group* is often compared to a group that is not changed—a group that did not receive the intervention—called the usual care or *control group.*

c. Researchers gather information about something that has already happened.

**Match the study type (left) with its correct description on the right.**

| | |
|---|---|
| **12.Qualitative Study** | a. Uses clinical tests, questionnaires or surveys to collect information which is recorded using numbers. Numbers are also used to report the results. This is the most common type of medical research |
| **13. Quantitative Study** | b. Often uses ideas and opinions collected first to determine what tests to then do for collecting results expressed in numbers. |
| **14. Mixed Results Study** | c. Information collected is often ideas, opinion, beliefs, attitudes and concerns and can be gathered via focus groups or interviews or oral histories. Results are reported in words and summarized into areas of thoughts called domains. |

COPD FOUNDATION

## Module 4: Designing, Doing and Sharing a Research Study

**Match the research study step (left) with its correct description (right)**

| | |
|---|---|
| **15. Identify a Problem** | a. Decide what information is needed, how this information will be gathered and measured, who can and cannot participate, where these participants will be found, how we will invite them and how long the study will last. |
| **16. Secure Funding** | b. Submit the research plan to an institutional review board for them to review and decide if the study's participants will be treated ethically. |
| **17. Get Permission** | c. Determine who can and cannot be in the study and develop "inclusion" and "exclusion" criteria, then use various ways to find and invite individuals to participate. |
| **18. Plan a Study** | d. Start with an idea, determine what has been done on the topic previously, focus the topic, develop a specific question to answer. |
| **19. Recruit Participants** | e. Look for groups interested in the topic, complete requests for proposals from foundations, government agencies, pharma companies or Patient-Centered Outcomes Research Institute. |

**Match the research study step (left) with its correct description (right)**

| | |
|---|---|
| **20. Consent Participants** | a. Collect samples or measurements from clinical tests, conduct surveys, interview participants, review medical records, keeping all information safe and confidential, at all times. |
| **21. Collect Information** | b. Review, summarize and draw conclusions from the data and answer, "Why did we get these results and what did they mean for the people in the study?" |
| **22. Conduct Analysis *(Statistical and Non-statistical)*** | c. Explain to potential study participants, in clear, simple language, the potential benefits and risks of participating in the study, along with sharing with them their patient rights. |
| **23. Evaluate Impact** | d. Publish the study's results/conclusions in a medical journal, present the results at a conference or share with other patients via a social network. |
| **24. Share Results** | e. Collect and analyze all information that can be measured and given a numeric value (quantitative) and information based on opinions, preferences and narratives (qualitative). |

**25. Which of the following is NOT an example of how you can contribute, as a patient/caregiver investigator, during a research study?**

a. Help develop the research question by sharing issues that frustrate, confuse or worry you in your daily life of living with COPD.

b. Voice concerns about what is being asked of patient to do during the study.

c. Conduct statistical analysis.

d. Write letters of support to funders, highlighting how important the research is to people living with COPD.

e. Provide your understanding of why the patients in the study reacted/responded the way they did.

## Module 5: Specific COPD-Related Research Information

**26. "Trajectory of COPD" research is research focused on how and why COPD progresses, over time from moderate to severe.**

a. True

b. False

**27. Research focused on the different "types" of COPD and the groups of patients who share common characteristics and similar disease progression is:**

a. COPD Treatment issues research

b. Implementation research

c. COPD Phenotypes

**Match the type of COPD research with its correct description**

| | |
|---|---|
| **28. Defining COPD** | **a. Research focused on moving results from studies and trials into daily practice.** |
| **29. COPD Epidemiology** | **b. Research focused on COPD oxygen issues, new medications, improved medications and new lung-based devices for treating COPD.** |
| **30. Treatment Issues** | **c. Research focused on the distribution, frequency, patterns, causes and risk factors of COPD.** |
| **31. Implementation Research** | **d. Research focused on the criteria used to diagnose COPD.** |

## Module 6: Key Types of Study Documents

**32. What is a research proposal? (choose all that make sense)**

a. A research proposal is a summary of a research project that is written to explain the research idea and how the research is to be done.

b. It can be used to request funding to carry out the research and to get other researchers to participate.

c. Research proposals can be written in response to a request or opportunity from a group that funds research like the National Institutes of Health or Patient-Centered Outcomes Research Institute or a Foundation.

d. All of the above

**33. A research proposal and a study protocol are just different words for the same document.**

a. True

b. False

**34. It is ok to ask, "does the research make sense?" and "are there any unneeded risks?" when reviewing a study protocol?**

a. True

b. False

## Module 7: Protections for Research Participants

**35. Please select the answer below that is NOT a role of the institutional review board.**

a. Reviews and approves all research before the study begins.

b. Ensures that people joining studies will be protected from unknown harm or risks.

c. Weighs risks versus benefits, looks at what protections are in place and if people in the study are informed about the study before they decide to join.

d. Conducts yearly reviews of all studies.

e. Any unexpected or serious study issues must be reported to the institutional review board.

f. Serves as a place for individuals participating in the study to share their concerns or complaints about the study.

g. Does the study and reports the results.

**36. The informed consent document is a binding contract and once participants begin a study they must continue it until the study is complete.**

a. True

b. False

**Match the term with its correct description**

| | |
|---|---|
| **37. Privacy** | a. Applies to the data and involves a person's identifiable information ad the security in place regarding who can see the information. |
| **38. Confidentiality** | b. Applies to the person, is an understanding that information an individual provides will not be shared with others without permission. |

**Overall Assessment:**
**ANSWER KEY**

**1. __b__** Research Advocate

**2. __c__** Patient/Caregiver Investigator

**3. __a__** Patient Advisor

**4. b, true**

***Explanation:*** A patient investigator participates as part of a research during ALL phases of the research study—from development of the research question through all steps in the process to the final evaluation and sharing of results phases.

**5. b**

***Explanation:*** Patient/caregiver investigators are not expected to know specifically how to design a research study, before joining a team. You will learn how a study is designed, as you participate and share your opinions, questions and experiences.

**6. d**

***Explanation:*** d is not true. You SHOULD ask questions—either of the entire team or of another investigator, one on one. Your opinions and perspective are important**.**

**7. b**

***Explanation:*** Experiential knowledge is not based on formal training. Experiential knowledge is all about one's personal experience.

**8. e**

***Explanation:*** All of the above. All of the questions listed are reasonable and appropriate questions to ask your study team before the start of the study. In addition, you may also

want/need to ask about logistics (how the team will communicate, if you will need to travel, etc.) and the roles and responsibilities for you and the other research team members.

**9. c**

***Explanation:*** *We will only be focused on research studies that involve people, specifically: patients and patient care givers like YOU.*

**10. c**

***Explanation:*** Observational studies have no change or "intervention" that occurs. Observational studies use existing information or new information obtained from observing, interviewing, surveying, etc.

**11. c**

***Explanation:*** Experimental studies involve a new intervention or change to a group of people, often in comparison to others. So, the answer "Researchers gather information about something that has already happened" is NOT TRUE for experimental studies—since this is not a new change or intervention.

**12. c**

***Explanation:*** Qualitative Study= Information collected is often ideas, opinion, beliefs, attitudes and concerns and can be gathered via focus groups or interviews or oral histories. Results are reported in words and summarized into areas of thoughts called domains.

**13. a**

***Explanation:*** Quantitative Study= Uses clinical tests, questionnaires or surveys to collect information which is recorded using numbers. Numbers are also used to report the results. This is the most common type of medical research.

**14. b**

***Explanation:*** Mixed Results= Often uses ideas and opinions collected first to determine what tests to then do for collecting results expressed in numbers.

**15. d**

***Explanation:*** Identify a Problem= Start with an idea, determine what has been done on the topic previously, focus the topic, develop a specific question to answer.

**16. e**

***Explanation:*** Secure Funding=Look for groups interested in the topic, complete requests for proposals from foundations, government agencies, pharma companies or Patient-Centered Outcomes Research Institute.

**17. b**

***Explanation:*** Get Permission**=** Submit the research plan to an institutional review board for them to review and decide if the study's participants will be treated ethically.

**18. a**

***Explanation:*** Plan a Study= Decide what information is needed, how this information will be gathered and measured, who can and cannot participate, where these participants will be found, how we will invite them and how long the study will last.

**19. c**

***Explanation:*** Recruit Participants= Determine who can and cannot be in the study and develop "inclusion" and "exclusion" criteria, then use various ways to find and invite individuals to participate.

**20. c**

***Explanation:*** Consent Participants**=** Explain to potential study participants, in clear, simple language, the potential benefits and risks of participating in the study, along with sharing with them their patient rights.

**21. a**

***Explanation:*** Collect Information= Collect samples or measurements from clinical tests, conduct surveys, interview participants, and review medical records, keeping all information safe and confidential, at all times.

**22. e**

***Explanation:*** Conduct Analysis= Collect and analyze all information that can be measured and given a numeric value (quantitative) and information based on opinions, preferences and narratives (qualitative).

**23. b**

***Explanation:*** Evaluate Impact**=** Review, summarize and draw conclusions from the data and answer, "Why did we get these results and what did they mean for the people in the study?"

**24. d**

***Explanation:*** Share Results= Publish the study's results/conclusions in a medical journal, present the results at a conference or share with other patients via a social network.

**25. c**

***Explanation:*** "Perform statistical analysis". You will not be expected to do this. A "statistics expert" on your team will perform the analysis and can provide you with a simple, plain language summary of the statistical conclusions—just ask.

**26. a, true**

***Explanation:*** Trajectory research looks at what happens over time—how COPD progresses from moderate to severe.

**27.c**

***Explanation:*** Phenotypes are types of COPD. Examples of COPD phenotypes are "emphysema-COPD with frequent exacerbations," "chronic bronchitis with rapid disease progression," etc.

**28. d**

***Explanation:*** Defining COPD= Research focused on the criteria used to diagnose COPD.

**29. c**

***Explanation:*** COPD Epidemiology= Research focused on the distribution, frequency, patterns, causes and risk factors of COPD.

**30. b**

***Explanation:*** Treatment Issues= Research focused on COPD oxygen issues, new medications, improved medications and new lung-based devices for treating COPD.

**31. a**

***Explanation:*** Implementation Research= Research focused on moving results from studies and trials into daily practice.

**32. d**

***Explanation:*** All of the answers listed are correct so "all of the above" is the best answer option. A research proposal is written to explain a research idea and how that research is to be done; it can be used to request funding; and research proposals can be written in response to a request or an opportunity from a group that funds research.

**33. b, false**

***Explanation:*** The research proposal and the study protocol are two different documents. The research proposal is an overview or summary and the study protocol provides exact details of what the research team is planning. Both documents are needed and created for a research study.

**34. a, true**

***Explanation:*** Both questions are good questions to consider when reviewing a study protocol. Other good questions include, "Overall is what is being asked of participants realistic?" and "Are people being paid for their time and effort?"

**35. g**

***Explanation:*** An institutional review board is *not* involved with the implementation (the "doing") or results reporting of a study, but rather serves as an independent group that reviews the study plans, ensures that participants' will be protected from harm, weighs risks versus benefit and serves as a place for reporting serious issues or concerns and complaints about the study.

**36. b, false**

***Explanation:*** The informed consent document is a *voluntary agreement* between the participant and the study team—it is not a contract and a participant absolutely has the right to *stop participating in a study at any time.*

**37. b**

***Explanation:*** Privacy= Applies to the person, is an understanding that information an individual provides will not be shared with others without permission.

**38. a**

***Explanation:*** Confidentiality= Applies to the data and involves a person's identifiable information and the security in place regarding who can see the information.