



MODULE 4

DESIGNING, DOING AND SHARING A RESEARCH STUDY

Overview of Module 4: Designing, Doing and Sharing a Research Study

This section will include:

Phases and Steps of Research:

- Before: Designing and Planning (4 steps)
- During: Doing the Research (3 steps)
- After: Sharing the Research (2 steps)

An example illustrating all phases and steps

Estimated Time Commitment: *30-45 minutes*



Instructions for Going through Module 4

You do not need to go through the module in one sitting. Feel free to take breaks and complete at your own pace.

We have broken the module up into 3 sections with suggested breaks:

Part 1 – *Phases of Research and Designing and Planning Phase*
(Slides 5 to 21)

Part 2 – *Doing Phase of Research* (Slides 23 to 39)

Part 3 – *Sharing Phase and Research Example* (Slides 41 to 55)

Key Terms Used in this Module

- You will hear a lot of **new terms** during this module that you might not know
- We do **not expect you to know what these terms mean right away or memorize them** – just to familiarize yourself with the words
- Here is a **link to the key terms** used in this module that you can reference as you go through - click [here](#)

Part 1

***Phases of Research and
Designing and Planning Phase
(Slides 5 to 21)***

Phases of Research



Generally, **all research** studies have **different phases**, or steps, to the research process.

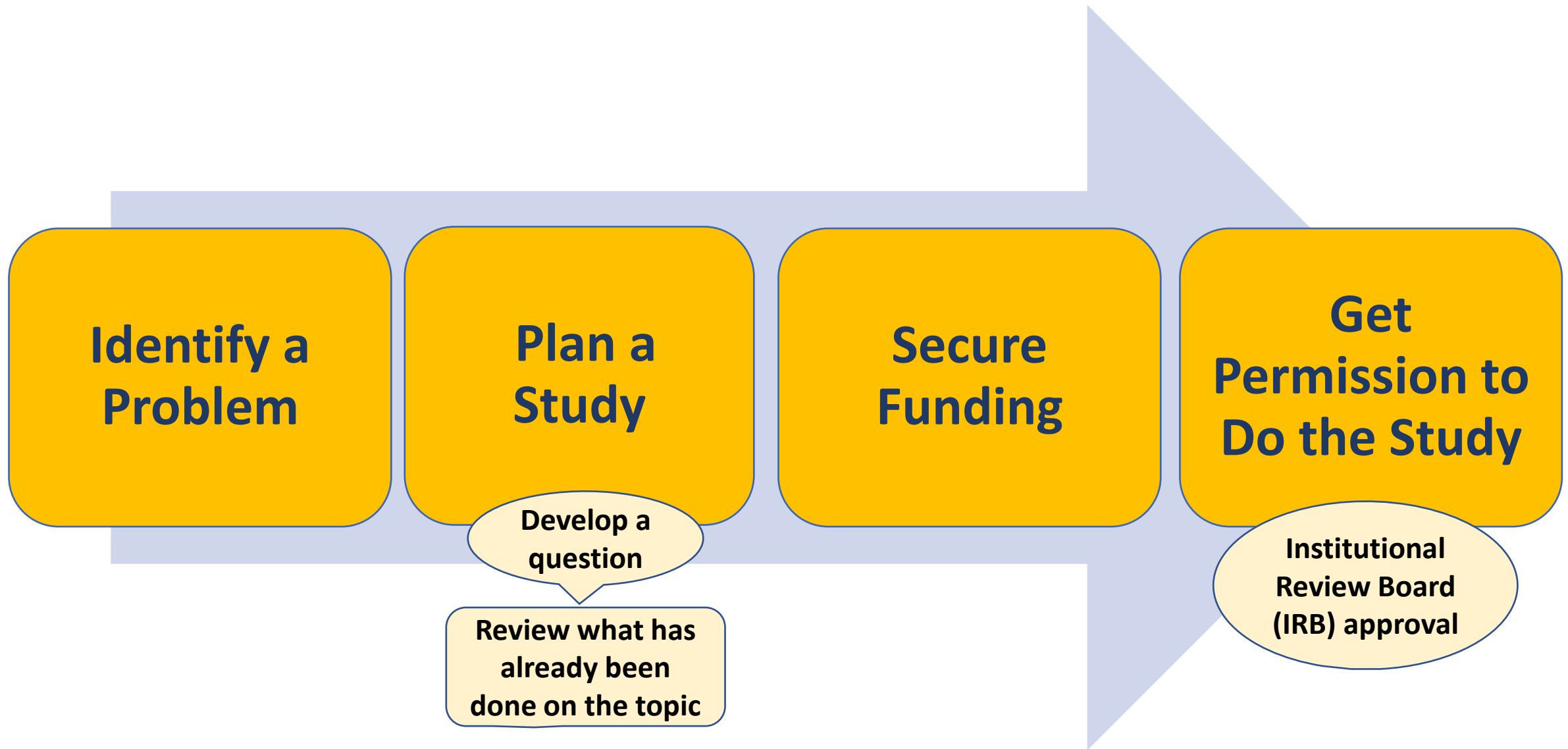
These can be divided into **3 general categories**:

- **Designing and Planning** (*Before*)
- **Doing the Research** (*During*)
- **Sharing the Research** (*After*)

Steps in the Research Process: **BEFORE**, **DURING** and **AFTER**—A Quick Intro

Identify a Problem	Starts with an IDEA , literature review— what has been published , then create FOCUSED topic and then a SPECIFIC Question
Plan a Study	What information do we need to answer our question? How/where/when will we get info? From whom?
Secure Funding	Government agencies? PCORI? Foundations? Pharma?
Ask Permission	Institutional Review Board process—required to ensure participants will be treated ethically
Recruit Participants	Who can and cannot be in the study? Find participants by advertising, posting fliers, making phone calls.
Consent Participants	Tell them the risks and benefits and their rights
Collect Information	Gather measurements , conduct interviews , review records ...etc
Conduct Analysis (Statistical/Non-Statistical)	Review, organize, understand all information — quantitative (<i>measured</i>) and qualitative (<i>preferences, perceptions, stories</i>)
Evaluate Impact	Did we answer our original question? Why or why not?
Share Results	Publish in a medical journal; present at a conference

Steps in the Research Process: PLANNING--*Before*



Steps in the Research Process: BEFORE

Identify a Problem or a Question to Answer



Start with an idea...

Conduct a **literature review** - *to discover what other studies have been completed on the topic and what is already known on the topic.*

Focused topic - *new research should have the potential to bring new knowledge on the topic*

Create a specific research question *(a question that research can answer) All research should be guided by simple, clear research questions.*

PICO Approach – Way to Evaluate a Research Question

A frequently used approach to looking at a research question is the **PICO Approach**

	Definition	Example
P	Population – who will be studied	People with COPD who have had a recent Emergency department visit
I	Intervention(s) – what is being tested (new medication, new way to do something)	Home-based Exercise Program
C	Comparator(s) – what is the intervention being compared to (usual care, placebo, other medication)	Individuals not in home- based exercise program
O	*Outcome(s) – what do we measure to find out if the intervention made a difference	Quality of Life Improvement per patient self-report

****What are Outcomes?***

Can be broken into primary and secondary – outcomes are often referred to as endpoints

- **Primary Outcome** – the main measure of the study on which the statistics are built – ensuring enough participants to reasonably detect an important difference
- **Secondary Outcome** – other outcomes that matter and will be measured – some may not occur frequently enough to determine a difference (statistically significant) but researchers should measure, e.g., in a study that targets preventing going to hospital (primary) other outcomes like death, patient satisfaction, cost might also be measured

Patient/Caregiver Investigator's Contributions



*How **you can contribute** during this “Identify a Problem” research step:*

- Patient/caregiver investigators often have **great ideas** of what needs to be studied
- Provide a **different view** than the researchers on what is **important to patients in the real world**
- These ideas may be based on issues **that frustrate, confuse or worry you in your daily life** of living with COPD
- You can share whether the potential research topics will **make a difference** in the lives of people living with COPD

Steps in the Research Process: BEFORE

Plan a Study



- What **information** do we need to answer the question?
- **How** will we gather the information?
- How will we **measure this information**?
- **Who can** and **cannot** participate in this research?
- **How will we find these people?** How many do we need?
- **How** will we **invite people**?
- **How long** will the study last?
- To **what will we compare** our results?

Patient/Caregiver Investigator's Contributions

*How **you can contribute** during this
“Plan a Study” research step:*

Consider these questions:

- Are the other researchers **considering all the concerns a patient may have** about what is being asked of them in the study?
- Do you **agree with the planned recruitment** efforts?
- Are the **study materials clear and written at a 6th grade** reading level?

Your voice is critical here.



Steps in the Research Process: BEFORE

Secure Funding



Look for **groups that are interested** in the topic.

Are there “**Requests for Proposals**” related to your topic or other **groups who share an interest in your topic**?

Federal Funders? (*National Institutes of Health, Centers for Disease Control and Prevention, Department of Defense, etc.*)

<https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts>

The Patient-Centered Outcomes Research Institute (PCORI)?

<https://www.pcori.org/funding-opportunities>

Foundations?

Example: <https://foundation.chestnet.org/grants/apply-for-a-grant/>

Pharmaceutical or device companies?

Steps in the Research Process: BEFORE

Secure Funding continued...



Securing funding may **require multiple steps** and can be **quite a lengthy process**.

- **Letters of interest** or intent may be due in 6 weeks;
- These are **reviewed** in 6 months;
- An **invitation to submit an application** occurs in the next 3 months;
- Then there is the **initial application for the funding**, which may require **3 to 9 months for feedback**;
- There may be a **resubmission** required;

Studies sometimes require multiple funders

How you can contribute during this “Secure Funding” research step:

- **Write letters of support highlighting how important this research is to people with COPD.**
- **Invite others to provide support or suggestions. If the potential funder is a foundation, do you know someone who gives to this foundation?**

Steps in the Research Process: BEFORE

Get Permission

- Submit Research Plan to an **institutional review board** (at a hospital, university or other) for review—to ensure participants' rights are protected.
- The institutional review board (often referred to as the “IRB”) will decide if **participants are being treated in a way that meets the accepted ethical standards.** *(you will learn more about this in Module 7 – Protections for Research Participants)*
- The **IRB will review all materials** including the study procedures, the informed consent, all materials given to patient participants and plans for dissemination of results.
- A member or **members of the research team may appear before the IRB** to explain the research plan and answer questions.
- The IRB approval process **can be a lengthy process with a few rounds of reviews.**

Patient/Caregiver Investigator's Contributions

*How **you can contribute** during this “Get Permission” research step:*

- Make sure that you have **reviewed all the materials** given to patients.
- Make sure that you have **reviewed the informed consent**.
- Make sure that you have **reviewed the plans to share the results** with the participants.

MODULE 4: REVIEW QUESTIONS (PART 1)

- The next few slides have some questions to help you review and remember what we have presented so far in this Module.
- This is not a graded test and is meant to only help you retain the information. There is an answer key at the end.
- Here is a link to the key terms that might help as you go through the review questions: click [here](#)
- If you have any questions, please email BRIDGE@copdfoundation.org



MODULE 4 - REVIEW QUESTIONS (PART 1)

1. Which answer below lists the four research steps that are done BEFORE the study begins?

- a) Identify a problem, gather information, plan a study, conduct analysis
- b) Identify a problem, plan a study, secure funding, get permission
- c) Identify a problem, recruit participants, gather information, conduct analysis
- d) Identify a problem, plan a study, get permission, gather information

Match the research steps with their descriptions:

2. 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.
3. 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.
4. Get Permission	c. Look for groups interested in the topic, complete requests for proposals from foundations, government agencies, pharma companies or PCORI.
5. 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.

MODULE 4 - REVIEW QUESTIONS ANSWER KEY (PART 1)

1. b “Identify a problem, plan a study, secure funding, get permission”

Explanation: Before a research study begins, the research team “identifies a problem”—what should be studied, then “plans the study”—the who, what, how of it all, then “secures the funding”—before going further, a study must be funded—there will be costs and these must be covered by funds from a government agency, foundation, pharma company, PCORI, etc., and then finally, before starting the study, the team must “get permission” from an institutional review board, this protects the participants and ensures that they are treated ethically.

2. d

3. c

4. b

5. a

Explanation: See slide 7 for a quick overview or slides 8-18 for a more in-depth review

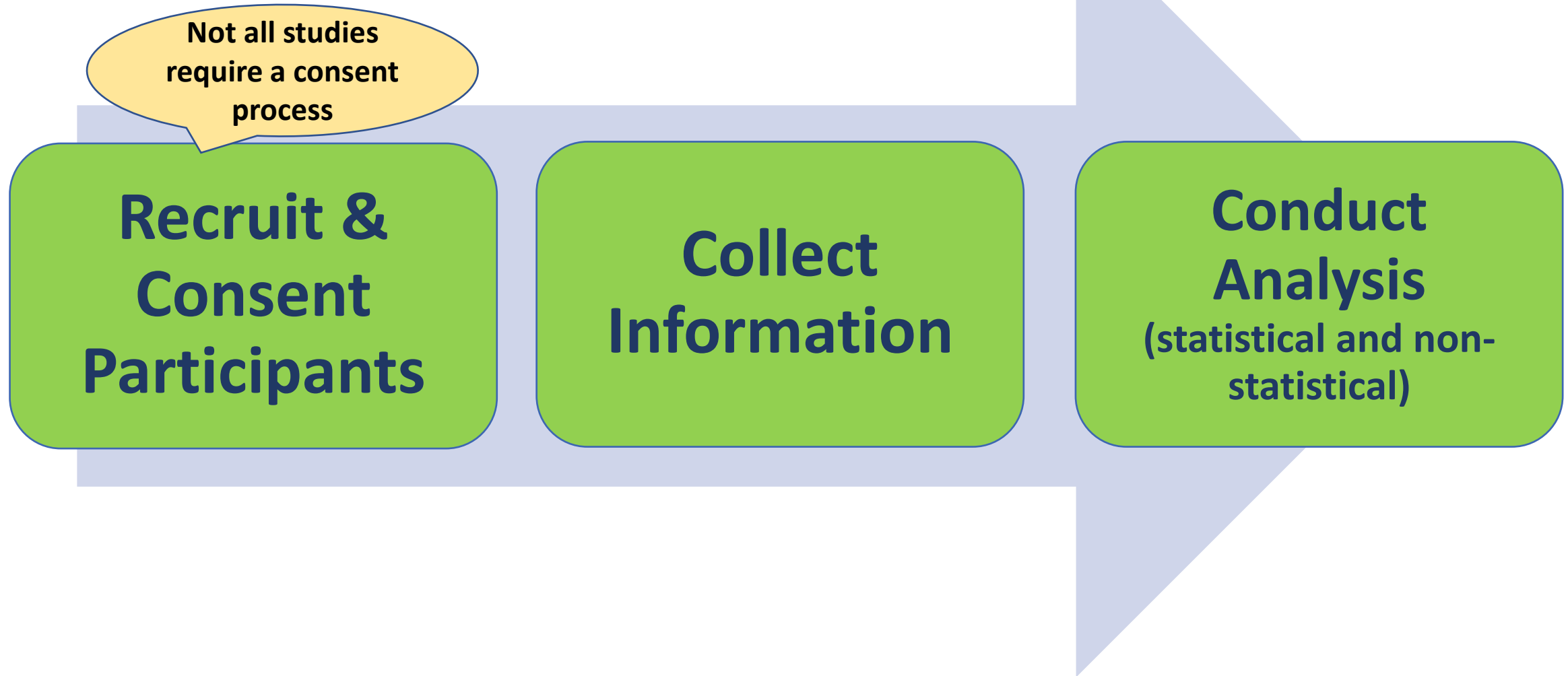
You completed Part 1 - Great job!
Feel free to take a break before going on to Part 2



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Part 2
***Doing* Phase of Research**
(Slides 23 to 39)

Steps in the Research Process: DOING-- *During*



Steps in the Research Process: DURING

Recruit Participants



During the Planning step, the research team decides **who can** and **who cannot participate** in a study. The team **develops “exclusion” and “inclusion” criteria**.

- **Exclusion criteria decisions:** based on what specific **issues a participant could have that might confuse the results** or make it unclear if the actual research topic was answered clearly. ***Example:*** patients on oxygen and patients with other health concerns may be excluded because these unique concerns may affect how the participant completes the study.
- **Inclusion criteria decisions:** based on the basic traits or behavior a **participant must have to make the research question answerable**. ***Example:*** Must have been diagnosed with COPD, must be at least 45 years old, etc.

Steps in the Research Process: DURING

Recruit
Participants
continued....

Following the exclusion and inclusion criteria, study participants may be recruited in any or all of the following ways:

- With flyers posted in clinics, physician offices and hospitals
- By telephoning individuals who meet all of the studies requirements (“inclusion criteria”)
- With notices/advertisements in local newspapers and on radio and television
- Registries like the COPD Patient-Powered Research Network



Patient/Caregiver Investigator's Contributions

*How **you can contribute** during this
“Recruit Participants” research step:*

Your input on the recruitment efforts will be very helpful

- Share what **would convince you** to join such a study.
- Help identify **potential problems** which might stop someone from joining a study.
- Do all the **recruitment efforts make sense** to you?
- Do you think **other patients will respond** to these efforts—**based on your own experiences?**
- **No suggestion is wrong**—recruitment often takes creative ideas that researchers may not think about.



Steps in the Research Process: DURING

Consent Participants

To “**consent participants**” means to tell participants about:

- the **potential benefits in clear language** without promising too much *and*
- the **potential risks of participating in the research** plan in language that is clear but not frightening *and*
- the **rights of the patient** in understandable, clear terms.



Steps in the Research Process: DURING

Consent
Participants
continued...

Some studies may NOT require written consent:

Epidemiological studies and other observational studies (*that we discussed in Module 3*)

- These **studies use existing data** from medical records, previous surveys, public health records, etc.

The research team **must still keep data safe, protected and confidential.**



*How **you can contribute** during this “Consent Participants” research step:*

- You can provide feedback on the “informed consent” form - **Does it make sense to *you*?**
- Is it written in a way that will be **understandable to most patients** and/or their families?

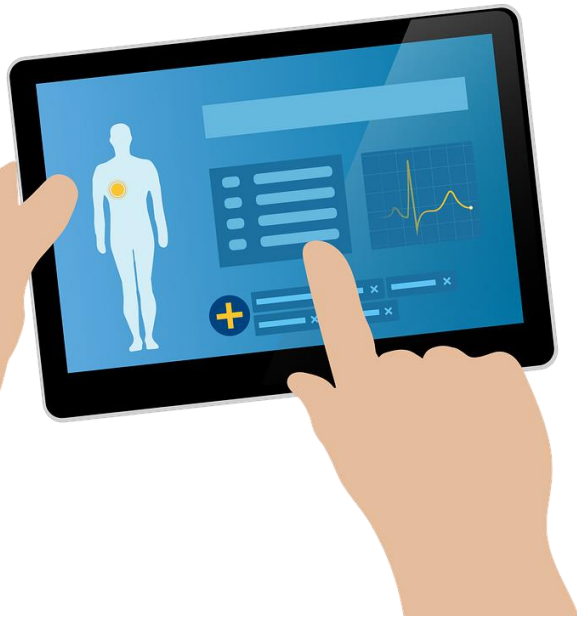
Steps in the Research Process: DURING

Collect Information

Data (information) can be collected:

- From **surveys**,
- By reviewing **medical records**,
- By **interviewing** participants,
- By **collecting samples or measurements**

Data **MUST** be kept **SAFE** and **Confidential** at all times!



Patient/Caregiver Investigator's Contributions

*How **you can contribute** during this “Collect Information” research step:*

- Is the **burden for the participant reasonable**, in terms of time required or any travel?
- Are the **materials in enough different languages**?
- Is there **enough reimbursement for time** required?

Steps in the Research Process: DURING & AFTER

Conduct Analysis

(Statistical & Non-Statistical)



During and after the study, the research team must **review, organize and attempt to understand** all of the information gathered...

Two types of information (data) may be collected and analyzed:

Quantitative—can be measured and given a numeric value and shown in tables and graphs

- ***Example:** Measure patients' lung function before and after taking a new medicine. Chart these measurements showing change over time*

Qualitative—based on opinions, preferences, observations, “narratives”—what is told or said via interviews or open-ended questions

- ***Example:** Interview patients about their experiences/observations while receiving the new medicine. Did patients have similar tales?*

During this “Conduct Analysis” research step:

- You will **NOT be expected to understand** the statistics involved in this step. *(However, as part of this training we are offering an Optional Module: Overview of Statistical Analysis)*
- Members of your team who are **statistics experts will complete this step** of the project.
- Don't hesitate to **ask for the statistical conclusions** to be provided to you **in simple, plain language**.

MODULE 4: REVIEW QUESTIONS (PART 2)

- The next few slides have some questions to help you review and remember what we have presented so far in this Module.
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MODULE 4 - REVIEW QUESTIONS (PART 2)

6. Which of the research steps listed below is NOT done “DURING” a research study?

- a) Recruit participants
- b) Consent participants
- c) Gather information
- d) Share results

7. Which of the answers below is a way of recruiting participants for a research study?

- a) flyer posted in clinics and doctor’s offices
- b) ads on radio, billboards and television
- c) phone calls to former hospital patients
- d) review of medical records to find individuals who meet the inclusion criteria
- e) all of the above

8. Select the answer below with the word that best completes this sentence:

“To consent a participant for a research study means to tell the potential participant about the *benefits* of participating in the study and the _____ of the study?”

- a) fun
- b) costs
- c) nick names of all of the research team members
- d) risks

MODULE 4 - REVIEW QUESTIONS (PART 2) CONTINUED...

9. True or false, as a patient/caregiver investigator on a research team you will be expected to conduct the statistical analysis of the study data?

- a) True
- b) False

Match the research steps with their descriptions:

10. Recruit 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
11. Consent Participants	b. Collect and analyze all information that can be measured and given a numeric value (quantitative) and information based on opinions, preferences and narratives (qualitative)
12. Collect Information	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
13. Conduct Analysis (Statistical and Non-statistical)	d. 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

MODULE 4 - REVIEW QUESTIONS ANSWER KEY (PART 2)

6. d “share results”

Explanation: The “Share Results” step does not happen DURING a research study—it happens after the study is over and the results have been analyzed and conclusions made.

7. e “all of the above”

Explanation: **ALL** of the ways mentioned –flyer, ads, phone calls and reviews of medical records—can be used to recruit research study participants who meet the “inclusion criteria”

8. d “risks”

Explanation: During the “Consent Participants” step, participants are told—in simple, easy to understand language—all of the benefits and potential “risks” of participating in the research study they are being invited to join. In addition, they are told of their patient rights, related to the study.

9. b “false”

Explanation: As a patient/caregiver investigator on a research team, you will not be expected to complete the statistical analysis of the study’s data—there will be statistical experts on your team who will be responsible for this process. You are also not expected to understand all of the statistical jargon/terms. However, if you want to familiarize yourself with some of the more commonly used statistical terms and concepts, an OPTIONAL Module: Overview of Statistical Analysis is offered.

MODULE 4 - REVIEW QUESTIONS ANSWER KEY (PART 2) CONTINUED...

10. c

11. d

12. a

13. b

Explanation: See slide 7 for a quick overview or slides 24-34 for a more in-depth review

You completed Part 2 - Great job!
Feel free to take a break before going on to Part 3



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Part 3
***Sharing Phase of Research and
Research Example***
(Slides 41 to 55)

Steps in the Research Process: SHARING-*After*

Evaluate Impact

Share Results

Steps in the Research Process: AFTER the study...

Evaluate Impact



- **Review the data collected**—when it is available.
- **Summarize** the data.
- **Draw conclusions** from the data.
- Answer “**Why did we get these results and what do they mean for people enrolled?**”
- Determine how well the **research plan answered the original question** and what next steps might be.

Patient/Caregiver Investigator's Contributions

How you can contribute during this “Evaluate Impact” research step:

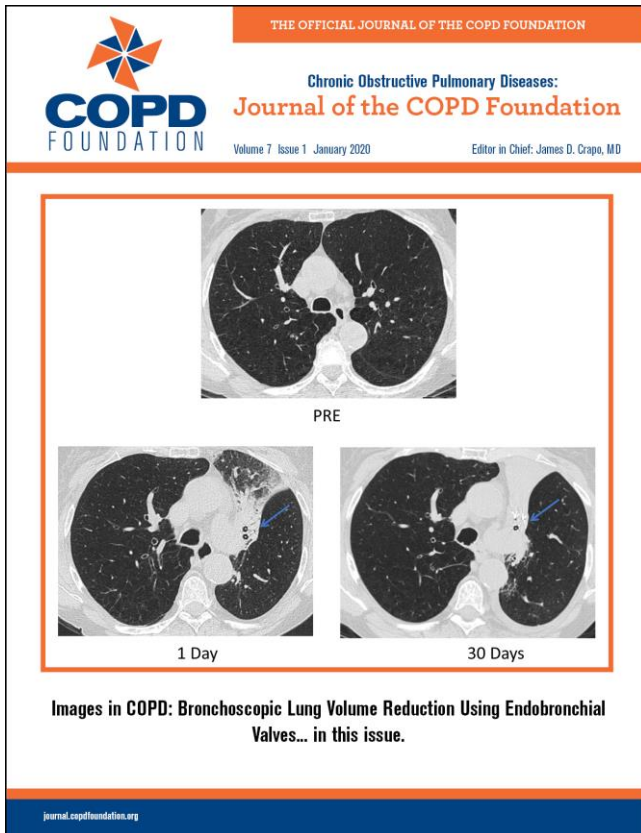
- Using your **experiences as a patient/caregiver**...how would **YOU** answer the **question** on the previous slide?
- Do you understand **WHY the patients reacted/responded the way they did?** Can you share this with the team?
- Did we **achieve the intended outcome?** Were there outcomes identified other than the ones that were stated in the beginning. Were there **additional impacts** from this study?

Your opinion and experiences are important—share them!

Steps in the Research Process: AFTER

Share Results

- Write and publish a **medical journal article**
- Present at a scientific/medical **conference**
- Share via the **internet/website**
- Develop **plain language summaries**
- **Identify places and methods to share the results and implications.**



Patient/Caregiver Investigator's Contributions

How you can contribute during this “Share Results” research step:

- Review summaries to make sure they are clear and use simple language
- Share the study and what you and your team learned with other patients:
 - in your support group,
 - in your social network,
 - at a patient-focused conference, etc.

Steps in the Research Process: **BEFORE**, **DURING** and **AFTER**—A Quick Review

Identify a Problem	Starts with an IDEA , literature review— what has been published , then create FOCUSED topic and then a SPECIFIC Question
Plan a Study	What information do we need to answer our question? How/where/when will we get info? From whom?
Secure Funding	Government agencies? PCORI ? Foundations ? Pharma ?
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Collect Information	Gather measurements , conduct interviews , review records ...etc
Conduct Analysis (Statistical/Non-Statistical)	Review, organize, understand all information —quantitative (<i>measured</i>) and qualitative (<i>preferences, perceptions, stories</i>)
Evaluate Impact	Did we answer our original question ? Why or why not ?
Share Results	Publish in a medical journal; present at a conference

Steps in the Research Process: Applied to an Example

To better understand the research process steps we’ve discussed, let’s apply them to a fictional example:

Research Step	Our Example: <i>A Study on COPD Patients and a Self-directed Chair-Based Exercise Program</i>
Identify a Problem	<p><u>The Idea:</u> Will COPD patients stick to an exercise plan that is self-directed?</p> <p><u>Literature Review:</u> Lots of published research on exercise programs for COPD patients</p> <p><u>Narrowing the Topic:</u> Decide to focus on <i>chair-based exercises</i> directed by an <i>onscreen instructor</i>—little published research on this. And this matches our interests best.</p> <p><u>Specific Research Question:</u></p> <p><i>“Can a self-directed exercise program featuring chair-based exercises provided via either a phone app or website help COPD patients exercise at least 3 times a week and will they do this for over 12 months?”</i></p>

Steps in the Research Process: Applied to an Example

Research Step	Our Example: <i>A Study on COPD Patients and a Self-directed, Chair-based Exercise Program</i>
Plan a Study	<p>What information will we collect? How often patients exercised and their health status and quality of life before and after the study.</p> <p>How will we gather this information?: Quality of life questionnaires before and after the study; lung function tests and exercise endurance tests before during and after the study. Participants will use exercise diaries to log how often they exercised.</p> <p>Who can be in the study (<i>inclusion criteria</i>) and who cannot (<i>exclusion criteria</i>) and how will we find them? COPD patients discharged in last 12 months from our emergency department, recruited via reviewing medical records and making direct phone calls.</p>
Secure Funding	<p>Is there a governmental agency or non-profit foundation interested in exercise programs for COPD patients? Are there “Requests for Proposals” related to this topic?</p>
Recruit Participants	<p>Where do we find individuals who match our “people who can be included” guidelines (<i>inclusion criteria</i>). Review medical records for COPD patient discharges in last 12 months. Recruit these individuals by making direct phone calls and asking them to participate.</p>

Steps in the Research Process: Applied to an Example

Research Step	Our Example: <i>A Study on COPD Patients and a Self-directed Chair-Based Exercise Program</i>
Consent Participants	<p>Help participants understand:</p> <ul style="list-style-type: none">• the benefits of participating in the study—they may find an exercise program they enjoy that improves their fitness and quality of life• the risks—very few risks as exercise program can be stopped at any point• their rights—they can stop the program at any time; talk with the research coordinator at any time; their medical information will be kept safe and secure at all times.
Collect Information	<ul style="list-style-type: none">• Measure participants' health status before and after the study with exercise endurance tests and lung function tests• Have participants answer quality of life questionnaires before and after the study• Have participants keep an exercise diary, writing down each time they do the chair-based exercises• Call participants every 6 weeks to encourage them and ask about their progress.• Interview participants at the end of the study—did they like the program?
Conduct Analysis (Statistical/Non-statistical)	<p>Use statistics to understand the quantitative information: the health status and quality of life questionnaires.</p> <p>Review and organize the qualitative information: the 6-week phone call interviews with patients and the end of study patient interviews.</p>

Steps in the Research Process: Applied to an Example

Research Steps	Our Example: <i>A Study on COPD Patients and a Self-directed Chair-Based Exercise Program</i>
Evaluate Impact	<ul style="list-style-type: none">• Did we answer our original question?• Did COPD patients use the chair-based exercise program regularly?• Did they like it?• If they did, did the program improve their overall fitness level?• Did it improve their quality of life?• Were there problems with the program that the patients helped us discover?• Is more study needed?• If so, what should be changed?
Share Results	<ul style="list-style-type: none">• Write a summary (manuscript) of the study and submit it for publication in <i>Chronic Obstructive Pulmonary Diseases: Journal of the COPD Foundation</i>.• Create a poster presentation of the study and present it at the American Thoracic Society's annual conference.• Talk about the study on COPD 360Social—explaining the conclusions to other patients



More on Clinical Research...

- Please pause and take a moment now to watch this video about clinical research. We hope you enjoy it.
- Link to European Patient's Academy video
- <https://www.youtube.com/watch?v=kOVryugeUco>

MODULE 4: REVIEW QUESTIONS (PART 3)

- The next few slides have some questions to help you review and remember what we have presented in the balance of this Module.
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MODULE 4 - REVIEW QUESTIONS (PART 3)

Match the research steps with their descriptions:

14. Evaluate Impact	a. 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
15. Share Results	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?"

16. True or false, in ALL of the steps to the research process, patient/caregiver investigators can play an important role and contribute to the process.

- a) True
- b) False

MODULE 4 - REVIEW QUESTIONS ANSWER KEY (PART 3)

14. b

15. a

Explanation: See slide 7 for a quick overview or slides 42-46 for a more in-depth review

16. a “true”

Explanation: In ALL of the steps of a research process, your voice is important and should be heard. You can play an important role and can contribute in each step. (yes, even in the “Analyze Results -statistical and non-statistical data” step). For a reminder of how you can contribute and why your voice is critical and should be heard, review slides 11, 13, 16, 18, 27, 30, 32, 34, 44 and 46.

LINKS TO KEY RESOURCES FOR MODULE 4

Below is a table with links to key resources and information that you might find useful

Takeaway Documents

- Glossary of Key Terms: click [here](#)
- Module 4 Review questions with answers and explanations: click [here](#)
- Chart of Steps in Research Process: click [here](#)
- Module 4 Summary Document: click [here](#)



Congratulations! You have completed Module 4

If you are interested in learning more about Statistics as mentioned in the Statistical Analysis Steps, please go on to the ***Optional Module -Overview of Statistical Analysis***

When you are ready, please go on to ***Module 5 - Specific COPD-Related Research Information.***

You don't have to do this right away – you can do it when you have time.

