# Research Ready

A workbook for clinical staff implementing research

lphi℠
ALIGNING ACTION FOR HEALTH℠

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# Research Ready

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## PURPOSE OF THIS WORKBOOK

More research is being done in clinic settings. Clinic staff are important to the success of research studies. This workbook was made to help clinic staff prepare to participate in research.

## HOW TO USE THIS WORKBOOK

This workbook is meant to be interactive. The authors recommend that you do the included activities as you read through the workbook. The answer key is on page 39.


What comes to mind when you think about research?
Have you ever participated in a research study as part of your job duties? What was it like?
Have you ever participated in a research study as a subject? What was it like?

# Part 1:
# What is Research?

## What is research?

**Research is a systematic process for discovering new knowledge.**

- When people have a new idea , they test it out, collect information, and make conclusions based on that information.
- Sometimes they conclude that their idea was correct. Sometimes they conclude that their idea was incorrect. And a lot of the time they conclude that their idea has points to explore further or in a different way.

**Nearly everything we know, we know because of research.**

- Things you use every day, like cars, cell phones, and cosmetics, were all developed using research.

**Research is especially important in healthcare.**

- Every medicine available today was researched before it was allowed to be put on the market.
- The FDA (Food and Drug Administration) uses information gathered from research to conclude whether or not a drug is safe and effective.

# What Is Pragmatic Research?

**Pragmatic research is an approach to doing research that brings research activities to the healthcare setting.**

- Traditionally, medical research took place in separate research centers. Patients had to go to another appointment at another location to participate in a research study.
- Pragmatic research combines research with the regular delivery of healthcare. This helps the researchers understand how the things they are testing work in a "real world" setting.
- Pragmatic studies must follow the same laws and regulations as any other type of health research study.

## Example of Pragmatic Research

**ADAPTABLE:**
**the aspirin study**

ADAPTABLE is a pragmatic study that is trying to learn which dose of aspirin is best for preventing heart attacks and strokes. Patients, doctors, and study coordinators helped to design the protocol for the study. Patients are enrolled into the study from healthcare providers in locations all over the United States.

# Why Pragmatic Research?

Not all studies need to be pragmatic research, but there are some key benefits of using this approach:

- It is easier for patients to participate in pragmatic studies. Pragmatic studies take place where patients already get their healthcare. No separate visits to a research center are needed.
- Pragmatic studies can help researchers include more types of people.

In traditional research studies, some types of people such as women and people of color are not always well-represented. There are many reasons why these groups don't participate in studies. Pragmatic research can help with some of those barriers.

Clinics themselves may benefit from participating in pragmatic studies. Doing studies can provide resources such as funding or equipment to the sites where the research takes place.

# Clinical staff are important!

**Clinical staff are key to the success of pragmatic studies. Your participation and cooperation can make or break a study. Here are some reasons why:**

- You are the front-line connection to the patients.
- You can perform key research tasks.
- Patients trust you.
- Patients are comfortable sharing information with you.
- You have the inside perspective on how a study is going.
- Your feedback is valuable to researchers.

# *The* BENEFITS *of* RESEARCH

Before you turn to the next page, take a moment to write down some of the benefits of research.

How can research benefit patients?_____

_____

_____

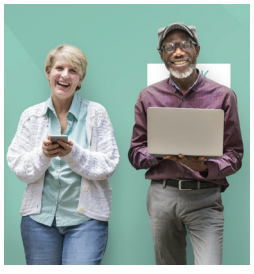
_____

How can research benefit clinics? _____

_____

_____

_____



How can research benefit your community and others?

_____

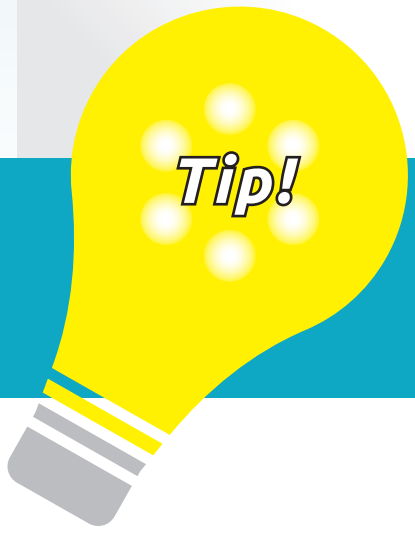
_____

_____

# The Benefits of Health Research

**Here are some of the benefits of health research:**

- Research is used to discover new treatments for diseases.
- Research is used to make sure that new treatments are safe for patients to take.
- Some research studies can give patients early access to promising new treatments.
- Research helps healthcare providers learn which treatments work best and which treatments are easiest to take.
- Research helps healthcare providers understand how treatments affect certain types of patients such as children or pregnant women.




*The rest of this book talks about research in general. The information applies to both pragmatic research studies and other types of health research.*

# FIVE REASONS

**patients choose to participate in health research studies:**

**Here are some of the reasons that patients say they participate in health research studies:**

I wanted to benefit others

To contribute to scientific research

To improve my own health

I received an incentive (like a gift card) to participate

My provider recommended it

# RESEARCH VS QUALITY IMPROVEMENT

Research has a lot in common with quality improvement. They both test ideas and seek to improve healthcare and ultimately improve patients' lives. But research and quality improvement are not the same thing and have important differences.

- **Research is done to share information with the world.** The information generated by research is often published in scientific journals or shared at professional conferences.
- **Quality improvement is done to inform an organization about its performance and operations**. The information generated by quality improvement projects are used to make changes to processes and protocols at a specific healthcare organization.

It's easy to sometimes confuse a quality improvement project with a research project.

- The differences between the two are sometimes very small.
- If you want to know if a project you're working on is research or quality improvement, it's OK to ask your supervisor or a member of the research team.

# Research vs. Quality Improvement

Here are some examples of quality improvement projects and research projects:

| QUALITY IMPROVEMENT | RESEARCH |
|---|---|
| One clinic site tests a new appointment reminder process for a week. If it goes well, the rest of the sites in the organization will use it. | Patients with lung cancer are offered the chance to enroll in a study to test a new treatment. |
| A health center decides to focus on screening more patients for depression in order to meet the goal set by an insurance company. | Patients with obesity are offered the chance to enroll in a study to try a new weight loss program to see if it works better than a standard program. |

## Which phrases describe research, and which describe quality improvement?

Draw lines to the correct answer for each of the words or phrases below:

- Organization's processes
- Share information with the world
- Internal operations
- Enroll in a study
- Publish results in a journal
- Improve only the organization

**Quality Improvement**

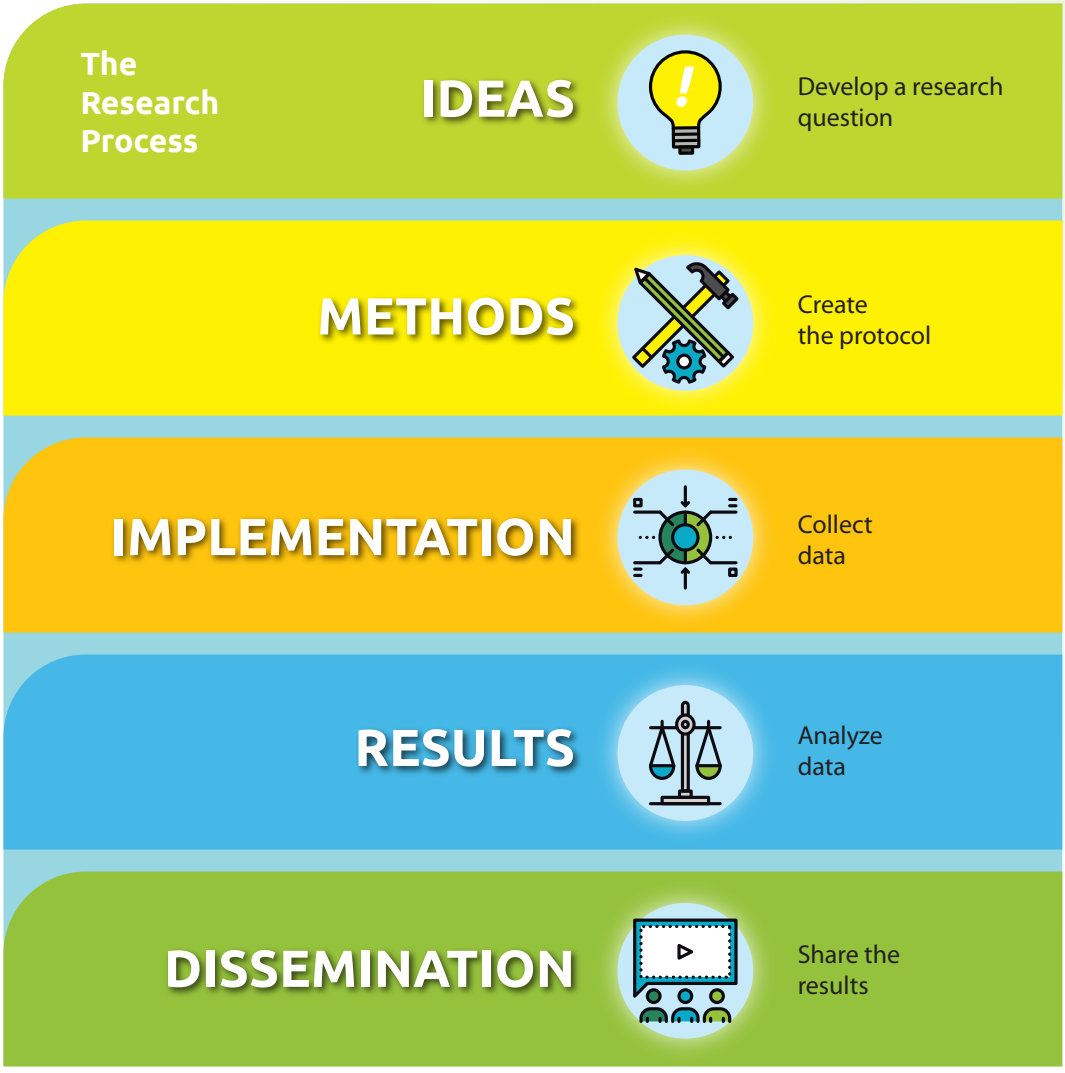
**Research**

Part 2

# The Research Process

All research studies follow the same basic process for creating new knowledge. The diagram below shows the main steps in a research study.

The rest of Part 2 will share more details about each of these steps.



# The Research Question

- The research question describes the purpose of the study by stating what the research study will try to understand.
- It sets the focus for the study so the researchers know what information they need to collect and what information is not related to their study.
- The research question helps the researchers stay on track when they write the protocol, collect the data, and analyze the results.
- Research questions are very specific and only focus on one small area of a larger issue.

Here are some examples of research questions:

**Question:**

*What side effects do patients experience from Experimental Drug #347?*

**Question:**

*How much weight will women over 50 with hypertension lose after 6 months of being on the DASH diet?*

**Question:**

*Are nutrition classes more effective at lowering cholesterol than statins in African Americans younger than 65?*

**Question:**

*Will text message reminders help people lose weight if they are not on any other weight loss program?*

# The Study Protocol

The study protocol is a document that describes how a clinical trial will be conducted.

- It is used to ensure the safety of the study participants and the integrity of the data collected.
- The protocol includes the objectives of the study and a detailed description of how the study will be done, including the inclusion and exclusion criteria and the data collection plan.
- The protocol is used to make sure that all sites who are doing the study do it in the exact same way.

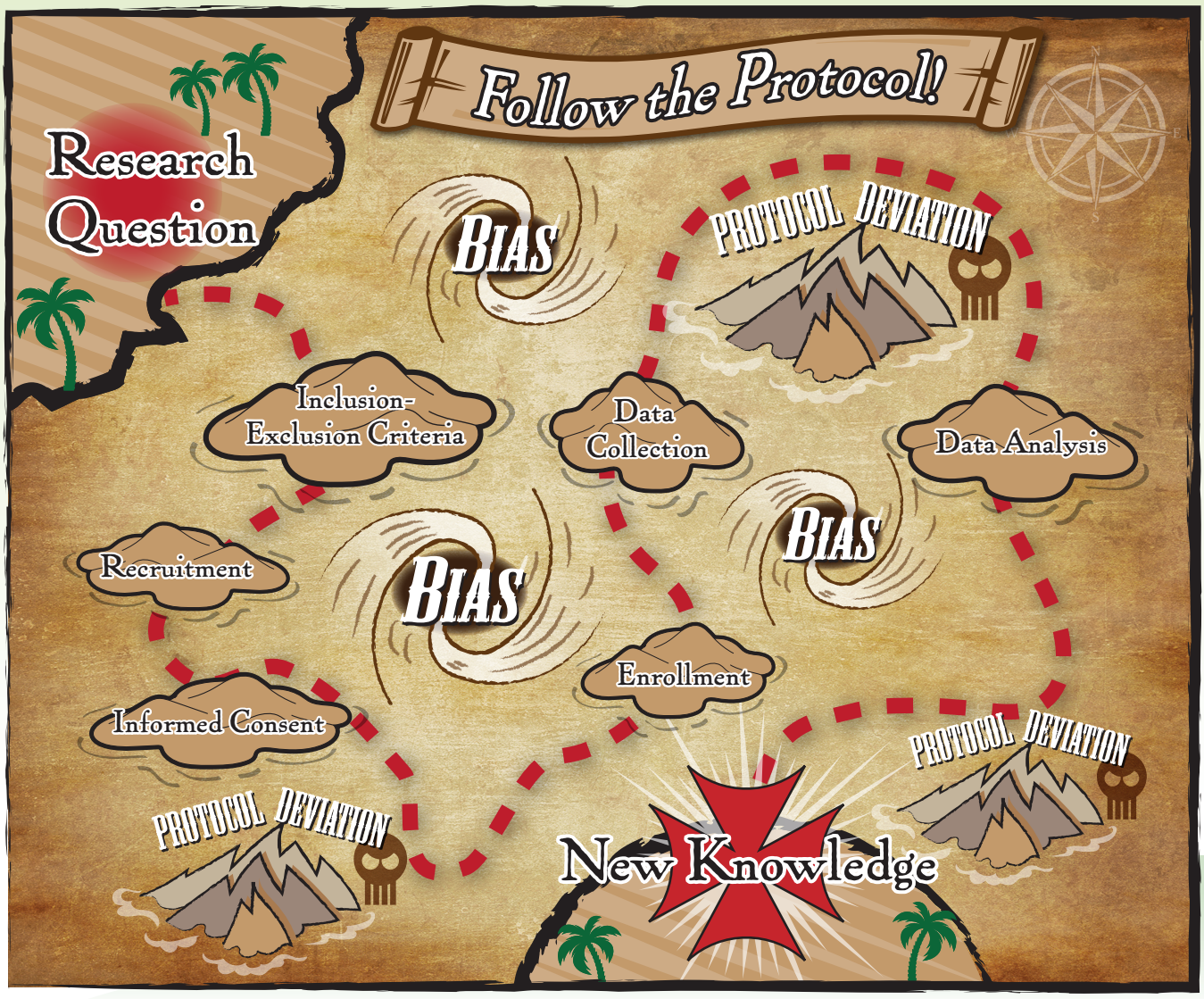
Clinic sites that are participating in the study will be given a copy of the protocol.

- In some cases, the researchers cannot share the full protocol. This is usually done to avoid bias. (See pages 28-29 for more on bias.)
- In most cases, you will not need to read the whole protocol. But everything that you are asked to do as part of the study is stated in the protocol and must be done that way.

# The Study Protocol

The study protocol *must* be followed exactly by everyone who is involved in the study.

- When the protocol is not followed, it is called a "breach of protocol" or "protocol deviation." All breaches must be reported to the research team as soon as they happen.
- The researchers are required to report all breaches of protocol to the institutional review board that oversees the study.
- If the breach of protocol is severe, any patients involved may be disqualified from continuing to participate in the study. In some cases, a severe breach of protocol can result in the whole study being stopped.



# Standard of Care

## Study Protocol vs Standard of Care

- A research study may require clinical staff to administer care differently from how you were taught.
- New discoveries can only be made if researchers can test new ideas that are different than the standard of care.
- As part of patient protection, the institutional review board (IRB) will review studies that provide care that is different from the standard of care.
    - The IRB must approve a study before it is allowed to begin.
    - If you are asked to give care that is not standard as part of a study, know that the protocol has been reviewed and approved for patient safety.
- Patients are made aware during the consent process that they may not receive the standard of care. The patients are informed of the risks and decide for themselves if they accept those risks and want to enroll.

**What is an example of non-standard care that a patient might receive in a study?**

# Inclusion and Exclusion

## Inclusion and Exclusion Criteria

Inclusion and exclusion criteria are used to describe who can participate in a study and who can't.

- These criteria must be followed so the researchers can make accurate comparisons related to their research question. Most research studies want to get information from people who have something in common like a certain medical condition (e.g. diabetes, cancer) or demographics (e.g. age group, sex, race). When the inclusion and exclusion criteria are not followed, the researchers' data is not valid and they cannot answer their research question.

  For example, if a study wants to include patients over the age of 50 and exclude patients 50 years and under, people who are in their 30s and 40s cannot participate. People younger than 50 are not relevant to the research question, and their data may skew the results to give an incorrect answer to the research question.

- Inclusion and exclusion criteria are also used to protect patients. If patients are excluded from a study, it may be because it is unsafe for them to participate.

  For example, if researchers know that their study drug has a dangerous interaction with metformin, then people who are taking metformin will be excluded from the study for their protection.

***Did you know?***

Inclusion criteria can be used to select participants who were under-represented in past research.

For example, the Health-E You study specifically included Hispanic adolescents to test if a computer program could improve their use of effective birth control.

# Inclusion and Exclusion Criteria

## Inclusion and Exclusion Criteria Practice

Based on the inclusion and exclusion criteria below, which patients can be enrolled in the study? Check yes or no next to their names.

**Inclusion criteria** (patient must meet all of these):
Female, age 18 or over, 10 or more migraines in the past year, and current or historic diagnosis of depression

**Exclusion criteria** (patient cannot have any of these):
Male, younger than 18, fewer than 10 migraines in the past year, or never diagnosed with depression

**Carlos**
◯YES ◯NO

Male, age 27, history of depression, 12 migraines in the past year

**Regina**
◯YES ◯NO

Female, age 45, history of depression, 11 migraines in the past year

**Kim**
◯YES ◯NO

Female, age 17, current diagnosis of depression, 25 migraines in the past year

**Amy**
◯YES ◯NO

Female, age 22, no history or current diagnosis of depression, 8 migraines in the past year

**Lois**
◯YES ◯NO

Female, age 59, current diagnosis of depression, 15 migraines in the past year

# Collecting the Data

Researchers can collect data related to their research question in a variety of ways, such as:

- Interviewing people (patients, medical staff, community members)
- Administering surveys or questionnaires
- Reviewing medical records
- Performing medical tests
- Making observations

Researchers may use a combination of methods to collect data or they might use just one method. All of the data for a study must be collected in the same way. The study protocol describes how everyone should collect the data.

Why do you think it's important to collect all of the data in the same way?

_____

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_____

_____

_____

How can people involved with the study know how to collect the data correctly?

_____

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# Analyzing the Data

Once the data has been collected, researchers can analyze it to see how it relates to the research question.

Researchers often aggregate the data they collect.

- Aggregate means that instead of looking at each subject's data individually, they group the data to look at a summary.
- Aggregate data helps the researchers make conclusions that apply to a larger population of people.
- Aggregate data also helps to protect patients' privacy by looking at a group of people instead of an individual person.

In order to know what the data says about the research question, researchers perform statistical analysis to compare it across different groups.

- This analysis is what the researchers use to get the answer to their research question.
- The process of statistical analysis can take a long time to complete. This is one of the main reasons why the results of a study are not available immediately after a study stops enrolling patients and collecting data. It can take months or even longer for the analysis to be completed and the results to be shared.

# Sharing the Results

It can take several months (sometimes even a year or more) for the results from a study to be shared.

- Some results may be published in scientific journals or presented at conferences.
- Many results are available online at https://clinicaltrials.gov
- Researchers may or may not share the results directly with the clinic sites that participated.
- If you want to know about the results, you can ask a member of the study team.

It can take even more time for research to change clinical practice and the standard of care.

- One study is usually not enough to change clinical guidelines.
- Doctors and health care administrators prefer to have information from multiple studies before changing the way patients are cared for.

*Articles in scientific journals can be expensive to download from the publisher's website. To get an article for free, try a public library, a college library, or contact the author to ask for a copy.*

# Research Takes Time!

One study is almost never enough to develop a new treatment or a new cure for a health condition. Multiple studies are needed.

The new studies build on the knowledge from previous research until the researchers, the government, and the medical community believe that there is enough proof to change the standard of care for patients.

Example: HIV PrEP

## Example: HIV PrEP (pre-exposure prophylaxis)

This timeline shows how long it took before PrEP was widely available for HIV prevention.

1995— Animal studies showed that tenofovir (one of the drugs in Truvada) could prevent simian immunodeficiency virus (SIV) infection in rhesus monkeys.

2002– Journal article published that proposed using HIV medications for PrEP.

2004—Truvada approved for treatment of HIV infection.

2005 –News articles reported that people at risk for HIV were buying HIV medications on the street to take for HIV prevention.

2007—First human studies of PrEP started.

2010—Preliminary results of iPrEx study published in *New England Journal of Medicine* showed that PrEP was effective in preventing HIV infection in men who have sex with men.

2012—Results of the Partners study published in *New England Journal of Medicine* showed that PrEP was effective in preventing HIV infection in heterosexual men and women.

2012—Truvada approved by FDA for HIV prevention in adults.

2012—World Health Organization recommended PrEP for men who have sex with men.

2014—CDC (Centers for Disease Control and Prevention) published comprehensive clinical practice guidelines for PrEP.

2015—WHO (World Health Organization) expanded PrEP recommendation to include all population groups.

2016—HPTN 083 study started to compare cabotegravir injections to Truvada pills for PrEP (this study is on-going and results were not available when this book was written).

2018—Gilead, the makers of Truvada, began airing TV commercials for PrEP.

Part 2

# Research Integrity

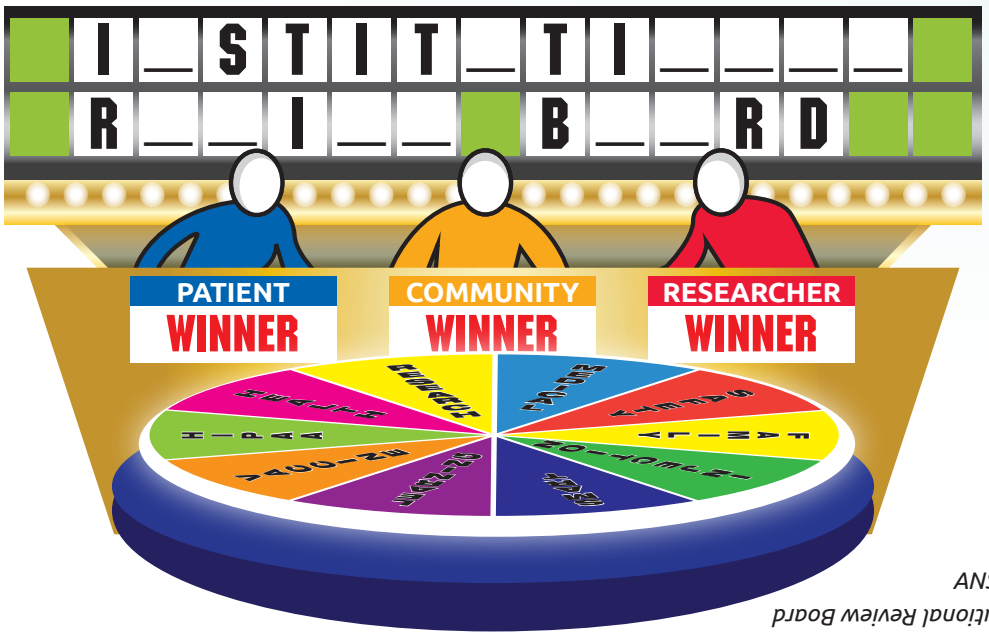
## Protecting Patients

Protecting the people who participate is an important part of every health research study.

- There are multiple groups responsible for protecting patients in research.
- Researchers must follow federal laws and regulations regarding doing studies on humans.

The Institutional Review Board (IRB) is the group that is responsible with ensuring researchers follow all of the rules for patient protection.

- The IRB reviews all research protocols before studies begin to make sure:
  - Patients' rights are protected
  - Risks to patients are minimal
  - Benefits are shared fairly
- After the study begins, the IRB continues to monitor the research to ensure that the approved protocol is followed and the patients stay protected.
- IRBs follow the rules set by the Food and Drug Administration and the Department of Health and Human Services. They may also choose to add their own rules if they feel more protection is needed.




*ANSWER:*
*Institutional Review Board*

# Privacy and Confidentiality

Protecting patients who participate in research also means protecting their privacy and confidentiality.

- Protecting your patients' privacy includes protecting the fact that they are participating in a study.
- The rules of HIPAA (Health Insurance Portability and Accountability Act) always apply when research is conducted in a clinic setting.
- Some research may include a HIPAA release, which means that the clinic can share protected health information with researchers. Each HIPAA release form will state what specific information may be shared and who it can be shared with.
- There are a few research-related activities that HIPAA does not cover.
  - In these cases, the IRB may grant a waiver of HIPAA authorization to give researchers permission to access limited patient information.
  - Most of the time, this information is used for study recruitment. Researchers may use information to find which patients are eligible and then get their contact information to invite them to participate in the study.
- If you are unsure of what information you can or cannot share, ask your supervisor or someone on the study team.

***What would you do?***

Tanya and Rosa are friends who both receive care at your clinic. Rosa recently enrolled in a new study. At her next visit, Tanya learns about the study and asks you if Rosa has enrolled.

How would you answer?

# Informed Consent

All patients who choose to participate in a study must complete an informed consent process.

- During this process, the patient is informed of the potential benefits and possible risks of participating in the study.
- It is up to the patient to choose whether or not to participate.
- Patients should never be pressured into either enrolling in a study or refusing to participate in a study.
  - Patients have the right to refuse to participate in a study for any reason.
  - Patients also have the right to participate in research studies that they qualify for.

## *Did you know?*

The term “informed consent” was first used in 1957 by a lawyer named Paul G. Gebhard. He was defending a doctor in a malpractice case.

# The Consent Process

During the consent process, someone from the study team will review the study information with the patient and have them sign a consent form if they want to enroll in the study.

- The consent form will contain information about the study and explain how the research team will keep patients safe.
- The consent form only covers one specific study and is not the same thing as a consent to treatment or a HIPAA release form.
- In most cases, the research staff (not the clinic staff) will consent participants into a study.

Even after the form is signed, the consent process is ongoing.

- This means that patients have the right to know what is happening to them at each step of the study and they can withdraw their consent at anytime.
- As part of ongoing consent, staff members should explain all research activities to the patient before they happen.
- Patients have the right to withdraw from a study at any time for any reason.

# AVOIDING BIAS IN RESEARCH

In research, the term “bias” refers to factors that incorrectly influence the outcome and conclusions of a study.

- Bias can happen at any point in the research process.
- Bias is dangerous because it can lead researchers to the wrong answer to their research question.
- Most of the time, bias is unintentional.

Examples of things that can cause bias include:

- Not following the inclusion and exclusion criteria
- Telling the patient that they are in the group receiving the new treatment
- Not asking all of the questions on a patient survey
- Only asking patients about side effects if they are on the new treatment
- Excluding a large portion of the target population from the study
- Patients not accurately remembering the time period the study asks about
- Only trying to recruit patients who you think will agree to enrolling

# Eliminating Bias

Researchers design their studies and methods to eliminate bias as much as possible.

- They try to make sure the patients who enroll in the study represent the target population that is affected by the research question.
- They also take steps to make sure that the study is done the exact same way by every location that is implementing it.
- Another precaution to avoid bias is called blinding.

  In a blinded study, the participants don't know if they are getting the experimental intervention or the standard intervention.

  In a double-blinded study, both the participant and their healthcare providers don't know which intervention the patient is getting.


Your clinic is part of a study to test if a new smartphone app can help people with diabetes monitor their blood sugar. Your job is to tell all of your patients with diabetes about the study while you check them in for their visit.

How can you avoid bias in this situation (check one)?

- ◯ A. Only tell patients about the study if you see them using a smartphone.
- ◯ B. Tell all of your patients about the study, regardless of whether you see them with a smartphone.
- ◯ C. Only tell patients about the study if they ask you for the information.

Part 4

# Working with the Study Team

## Balancing Clinic Work and Research Tasks

Clinics are busy places where everyone has a lot to do. Adding a research study will add more work, but it can be done efficiently.

The new research tasks need to be integrated into your current workflow in order for the study to work well. It can take time to find the right balance between your regular job duties and the research study.

Here are some ways to make it easier to incorporate a study into the flow of your clinic:

- Talk with your supervisor and the study coordinator to figure out how to fit the new study tasks into your daily routine and overcome challenges of adding them. It is best to discuss this with the research team before they start the study, so they can keep your concerns in mind when they write the study protocol.
- Keep the research goal in mind. The extra work you are doing is needed to advance healthcare discoveries. The study would not have been funded or approved if the research question wasn't important.
- Remember that you can make the difference. The work you do can be what determines if a study succeeds or fails.

# What Will I Be Doing?

What activities do you think clinical staff are responsible for during a study? Write your ideas below.

## *Did you know?*

Did you know?

The Framingham Heart Study is an ongoing, long-term study to investigate the risks linked to heart disease.

- The study helped uncover the links between smoking, physical activity, and blood pressure to heart disease.
- The study created the term "risk factor."

# Examples of Research Tasks

There are many ways that clinical staff can assist with a pragmatic study. Here are some examples:


Which of the tasks above do you already do as part of your job even if it's not for a research study?

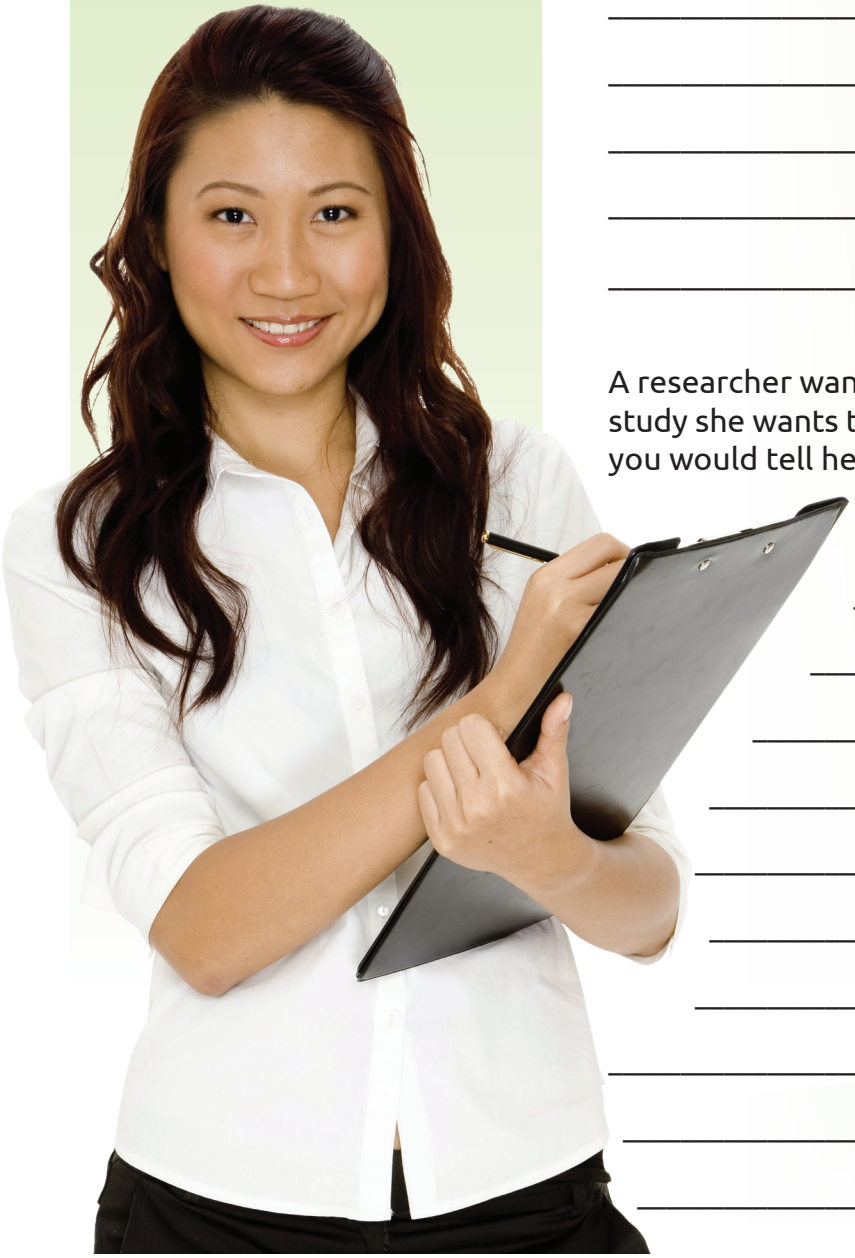
Make a check next to the ones that apply.

How many tasks did you check? _____

# What Would You Do?

Your clinic will be a site for a new pragmatic research study. Some of your co-workers are very opposed to the idea.

What would you say to them to convince them that doing research at your clinic is a good idea?



A researcher wants to meet with you to talk about a new study she wants to do at your clinic. What are three things you would tell her to consider when writing the protocol?

# The Study Team

The study team is the group of people who design the research study, manage it, analyze the data, and share the results. Most study teams have the following members:

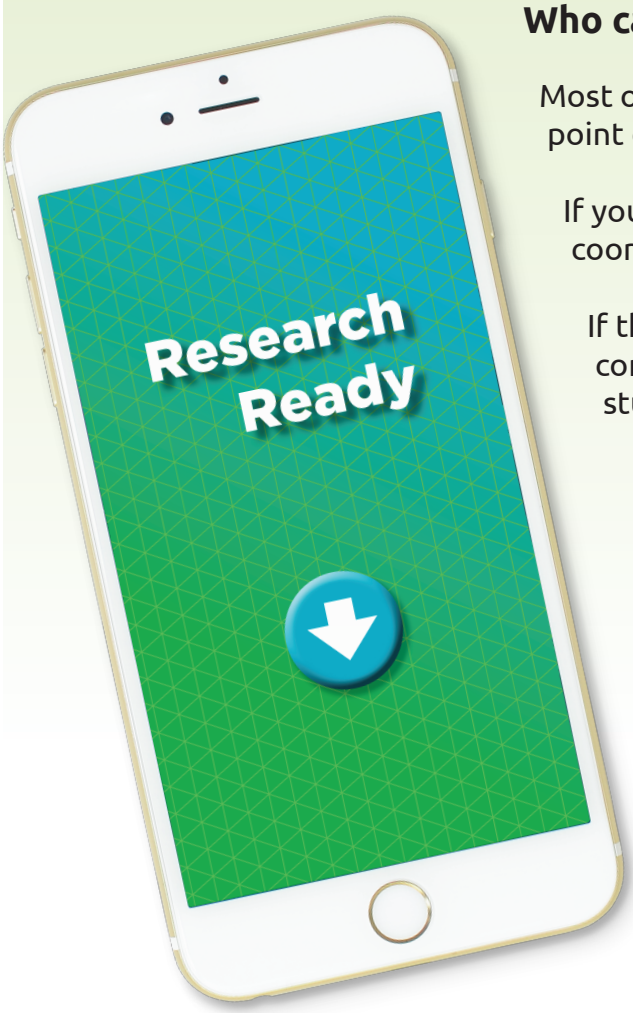
**SPONSOR**—pays for the research to be done (can be a university, pharmaceutical company, government agency, etc.)

**PRINCIPAL INVESTIGATOR (PI)**— designs and directs the study; analyzes data and makes conclusions

**SUB-INVESTIGATOR**—assists the principal investigator

**STUDY MANAGER**—manages the implementation of the protocol

**STUDY COORDINATOR**—works with study sites to collect data, answer questions, and solve problems




## Who can you contact?

Most of the time, the study coordinator will be your main point of contact for a research study.

If your concerns are not being addressed by the study coordinator, you can contact the principal investigator.

If the principal investigator also doesn't address your concerns, you can contact the IRB that oversees the study or your organization's compliance department.

# The Study Team

## Two-way communication is important!

The study team should share information with you, and you will have important information to share with them.

What you should tell the study team:

- Feedback on what is and is not working in doing the study
- Patient questions and concerns
- Reasons why patients are not doing well on the study or want to quit (e.g. side effects)
- When patients have medication changes, like starting a new medicine, changing the dose of a current medicine, or stopping a medicine
- When patients have other changes in their status such as pregnancy or a new diagnosis
- If patients are not compliant with study medications

What the study team should share with you:

- What the research team expects from the clinic
- Information materials about the study for staff and patients
- Information and clarification about the study protocol
- Explain what information the research team can and cannot share about a study (i.e. if the study is blinded)

# Can You Hear Me Now?

Tips for how to communicate with the study team:

- Know who your study coordinator is and how to contact them. Get their e-mail address and phone number!
- Try to have regular check-ins either in-person or on the phone.
- Speak up about issues or problems that you or your patients are having with the study.
- Ask for information or clarification when you need it.
- Tell the team if there is a breach of protocol as soon as it happens.

If you're not sure if you should tell the study team about something, tell them and they will decide if they need to act on it.

Part 5

# Summary and Quiz

## Summary

Here are the key points to remember about research in clinic settings:

- Research is how we get new knowledge.
- Pragmatic research brings research into the real world.
- Patients are protected by federal laws and institutional review boards.
- The study protocol gives instructions for how to do the study and must be followed by everyone.
- Clinic staff are the key to the success of pragmatic studies, even if they are not involved in all of the study activities.
- You can make a difference in healthcare by helping research move forward toward finding answers and better ways to care for patients.

# QUIZ

1. Whose rules does the IRB follow? _____

_____

_____

2. What act ensures patients privacy and confidentiality? _____

_____

_____

3. What type of data are the summary of the results of a study? _____

_____

_____

4. What type of activities are used to make internal changes at your organization?

_____

_____

5. Name the five steps in the research process. _____

_____

_____

6. The document that describes how the study will be done is called the study: _____

_____

_____

7. What information tells you which patients can enroll in a study? _____

_____

_____

8. Give an example of something that can cause bias. _____

_____

_____

9. Give an example of when you should contact the study team. _____

_____

_____

10. What is pragmatic research? _____

_____

_____

11. List 3 benefits of research. _____

_____

_____

12. How can you find out the results of a study you worked on? _____

_____

_____

(Answers are on the next page.)

**Workbook Answers:**

Page 2: No wrong answers! These are your opinions and your experiences.
Page 7: There are many correct answers for each question. Here are some examples:
**Patients:** new treatments, better treatments, incentives for participating
**Clinics:** improved reputation, incentives for participating, offering new treatments to patients
**Community:** better understanding of health, better treatments
Page 11: **Quality improvement:** Organization's processes, internal operations, improve only the organization
**Research:** Share information with the world, enroll in a study, publish results in a journal
Page 16: There are many correct answers. Here are some examples: new medicine, different dose of medicine, new medical device, delay treatment, start treatment sooner.
Page 18: Regina and Lois can be enrolled in the study.
Page 19: All of the data in a study must be collected the same way so that it can be compared. If the data is collected in different ways, the researchers can't explain what is causing the results. People involved with the study can find out how to collect the data correctly by reading the study protocol.
Page 25: Rosa's information is private, including what studies she enrolls in. Explain to Tanya that you can't tell her whether or not Rosa has enrolled.
Page 29: B. Tell all of your patients about the study, regardless of whether you see them using a smartphone.
Page 31: There are many correct answers. See page 32 for examples.
Page 32: This answer will be different for everyone depending on your current job duties.
Page 33: There are many correct answers to both questions. Here are some examples:
**Tell your co-workers**—Research can help his patients. Research can help his community. He already does the same tasks the researchers are asking him to do.
**Tell the researcher**—The extra time needed for the research activities. What your current workflow is and where the best place is to add research activities. Whether your patients are the right population for this study.

**Quiz Answers:**

1. Food and Drug Administration and Department of Health and Human Services
2. HIPAA (Health Insurance Portability and Accountability Act)
3. Aggregate
4. Quality improvement
5. Ideas, Methods, Implementation, Results, Dissemination
6. Protocol
7. Inclusion criteria or study protocol
8. (See page 28)
9. (See page 34-35)
10. Research done in the "real world"
11. (See page 8)
12. Go to clinicaltrials.gov, look up the journal article, and/or ask the study team.

# NOTES

# Research Ready

A workbook for clinical staff implementing research