# Participant-Centered Informed Consent

**Estimated completion time: 95 minutes**

OASH Office for Human Research Protections

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# Introduction

## Welcome!

To improve consent forms, we'll discuss:

- Key points to consider.
- Specific writing strategies.
- Examples and interactive exercises.

Hello! This training opportunity is a resource for the research community to help improve the quality of study consent forms. It includes key points to consider, specific writing strategies to use, and examples and interactive exercises to illustrate those strategies.

## Who Is This Training For?

**Anyone in the research community who plans, writes, or reviews consent forms for research involving human participants.**

- Researchers.
- Members of research teams and Institutional Review Boards (IRBs).
- IRB administrators.
- Study funders.
- Other institutional staff who may contribute to the writing of consent forms (for example, legal, compliance, or communications staff).

This training is intended for anyone who plans, writes, or reviews consent forms for research involving human participants. This includes the entire research community: researchers, members of research teams and Institutional Review Boards, or IRBs, IRB administrators, and study funders, as well as other institutional staff who may contribute to the writing of consent forms, such as legal, compliance, or communications staff.

## What Will This Training Do?

**Show a participant-centered approach to creating consent forms.**

This approach aims to:

- Help people better understand the research and their decision about participation.
- Promote trust and engagement in research.

This training will help the research community create, design, and review consent forms or templates for research participation in a way that helps participants understand the content and anticipates their needs. This participant-centered approach helps people understand the research and how the decision to participate or not might impact them personally. When we help people make informed decisions about research participation, we promote public trust and engagement in research.

## What This Training Is Not About

**The goal of this training is not to explain or provide a comprehensive overview of the regulatory requirements at 45 CFR 46 or to provide guidance on those requirements.**

Select the links below to review the regulations and related guidance materials on OHRP's website:

Common Rule Regulations

Human Research Protection Foundational Training

This training will reference the regulatory requirements for informed consent in the Common Rule at 45 CFR 46, subpart A. But the goal of this training is not to explain or provide a comprehensive overview of these requirements or to provide guidance on them. Refer to the Office for Human Research Protections, or OHRP, website to review regulatory information and related guidance materials. You can also complete OHRP's Human Research Protection Foundational Training for more information.

## Training Structure

This training is divided into six modules. Please note that you must complete all six modules to receive a completion certificate.

1) **Module 1: How Can We Improve Consent Forms?**

   - How do we **protect human research participants?**
   - What is the **purpose of informed consent?**
   - Why is it important to **consider your audience** when communicating with them?
   - How does a **participant-centered approach** improve consent forms?

2) **Module 2: How Do I Use a Participant-Centered Approach?**

   - What makes consent forms **meaningful** for potential participants?
   - How do potential participants **interact with and react to consent forms?**
   - How does **providing context** help potential participants make informed decisions?

3) **Module 3: How Can I Write Better Consent Forms?**

   - How can you convey information to potential participants **clearly and concisely?**
   - What does it mean to **choose words intentionally?**
   - How can you assess the **readability** of your consent forms?
   - How do you **revise overly long, complex sentences?**

4) **Module 4: How Can I Organize Information in Consent Forms?**

   - How can you help potential participants **locate and understand critical information**?
   - How do you present information in a **meaningful order** for potential participants?
   - What can you do to make **section headings** more useful to readers?

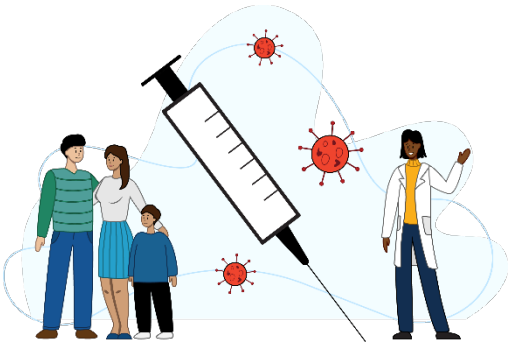
5) **Module 5: How Can I Design Consent Forms?**

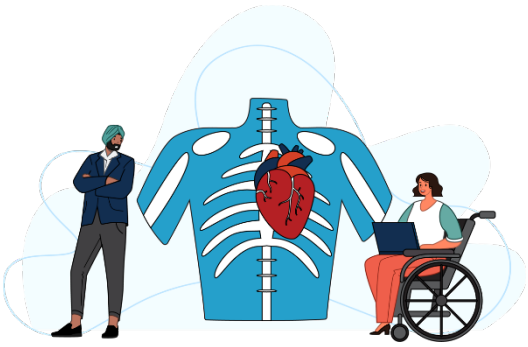
   - How can you help potential participants **navigate consent forms visually**?
   - What's the most effective way to use **color and graphic elements**?
   - How can you **visually represent numbers and data**?

6) **Module 6: Wrap-Up and Final Activity**

   - How do we put everything together to **improve future consent forms**?

# Module 1: How Can We Improve Consent Forms





## Module 1 Learning Objectives

**You will be able to:**

- Identify the central ethical principles for protecting human research participants.
- Identify the purpose of informed consent.
- Explain why we want to carefully consider our audience when communicating with them.
- Describe how a participant-centered approach improves consent forms.

After completing this training module, you will be able to identify the central ethical principles for protecting human research participants, identify the purpose of informed consent, explain why we want to carefully consider our audience when communicating with them, and describe how a participant-centered approach improves consent forms.

## The Belmont Principles for Protecting Research Participants

Three basic ethical principles to govern the conduct of biomedical and behavioral research involving human participants.

**Respect for Persons**

**Beneficence**

**Justice**

Learn more about the Belmont Report

> The National Research Act of 1974 created a commission that identified three basic ethical principles to govern the conduct of biomedical and behavioral research involving human participants, which they published in the 1979 Belmont Report. These principles are respect for persons, beneficence, and justice, and they serve as the ethical foundation for a comprehensive set of federal regulations known as the Common Rule. Nearly 20 federal departments and agencies follow the Common Rule to protect participants in the research they fund or conduct.

## Respect for Persons

**To respect someone is to give appropriate weight to the person's opinions and choices.**

Seeking informed consent shows respect by ensuring potential participants have the information they need to make an informed decision about participation.

The Belmont principle of respect for persons underlies the importance of informed consent. It acknowledges that individuals make decisions about how they want to live their lives and further their own interests. To respect someone is to give appropriate weight to the person's opinions and choices. In seeking informed consent from potential research participants, we honor our ethical obligation of respect for persons by ensuring they have the information they need to make an informed decision about participation.

## The Regulatory Requirement for Informed Consent

**In most cases, researchers must:**

- Seek informed consent prior to research participation.
- Ensure participation is truly voluntary.
- Clearly communicate information a reasonable person would want to make an informed decision.
- Start consent forms with a key information section and include certain types of information.

Common Rule Regulations

**Consent forms aren't just a list of requirements to check off!**

The Common Rule supports the ethical principle of respect for persons in research. Typically, researchers are required to go through the informed consent process with participants or their legally authorized representatives before involving them in research. Researchers must seek informed consent in ways that ensure participation is truly voluntary. They must provide easy-to-understand information that a reasonable person would want to know to make an informed decision. Consent forms typically start with a concise summary of key information about study participation and must include certain types of information required by the Common Rule. Remember that the consent form isn't just a list of requirements to check off. A study's consent form requires thought and effort. Informed consent is often not a one-time interaction but an ongoing process of communicating respectfully with research participants throughout their participation.

## Fulfilling the Purpose of Informed Consent

Consent forms should **empower potential participants** to make informed decisions.

| | |
|---|---|
| **How?** | Create **participant-centered consent forms —** that is, forms that are **understandable** and **meaningful** to your potential participants. |
| **Why?** | Unclear consent forms risk **undermining our relationships** with participants and **hampering study recruitment and retention**. |

Consent forms should empower potential participants to make informed decisions by giving them the information they need in a way that's understandable and meaningful, or, in other words, in a participant-centered manner. Remember: we don't write consent forms just to fulfill a regulatory requirement or to protect against legal liability — we write them to help people make decisions and to earn their cooperation. And when we don't commit the time and effort to create clear, participant-centered consent forms, we risk undermining our relationships with participants and hampering study recruitment and retention.

## Common Problems with Consent Forms

- Too much information and unnecessary details.
- Overly complex language.
- Dense formatting with minimal white space.
- Written for scientific reviewers.
- Disjointed content copied directly from research protocols or grant applications.
- Complicated legal-sounding language in passive voice.

**These problematic practices:**

1) Do a disservice to participants.
2) Prevent us from fulfilling our ethical obligation of respect for persons.

Unfortunately, consent forms often contain an overwhelming amount of information and unnecessary details. They also tend to use overly complex language and dense formatting with minimal white space. Many consent forms read like they were meant for scientific reviewers, with disjointed content copied directly from research protocols or grant applications. Others read like they were meant for lawyers, with complicated defensive-sounding sentences in passive voice. These common problems result in consent forms that many potential research participants have trouble reading and understanding. When this happens, we are doing a disservice to our potential participants and we are not fulfilling our ethical obligations related to informed consent and respect for persons.

## How Can We Do Better?

**Know your audience**

Understand how potential participants may receive information about the research. Our understanding of the audience shapes the content and the tone we use to present information.

**Communicate clearly**

Use common, everyday language and format consent forms in ways that make them easier to read and understand.

**Organize information**

Organize your consent forms in a way that helps potential participants understand what information is most important to them, i.e., the information most likely to affect their decision to participate. Begin by summarizing the key information and provide more details later in the consent form.

## Consent Form Templates

**Templates *can* help by providing a standard layout and guiding researchers.**

| | |
|---|---|
| **Problem?** | **Densely formatted** and **one-size-fits-all** templates contribute to common problems with consent forms. |
| **Solution?** | Use **participant-centered layouts**, prompts for the **correct levels of detail**, and examples of **easy-to-read language**. |

Consent form templates can help by providing a standard layout and guiding researchers to include all required information. But when the templates are densely formatted and use a one-size-fits-all approach to content that varies across studies, they contribute to common problems with consent forms. Templates can be improved using the strategies in this training, including participant-centered layout, prompts for the correct level of detail, and examples of easy-to-read language. Tailoring consent templates to different types of research can further support the participant-centered approach.

## What Can IRBs Do to Help?

**IRBs review and approve consent forms used for research regulated by the Common Rule.**

- Ensure that forms provide the information potential participants need.
- Check that the information is clear and easy to understand.
- Use the strategies in this training to suggest revisions.

It is a general requirement for research regulated by the Common Rule that the IRB reviews and approves consent forms used for research participation. IRBs must ensure that these forms provide the information that potential participants need to make informed decisions in a way that's clear and easy for them to understand. IRBs can use all the strategies in this training to suggest revisions to confusing or overly complex consent forms.

## Module 1 Conclusion

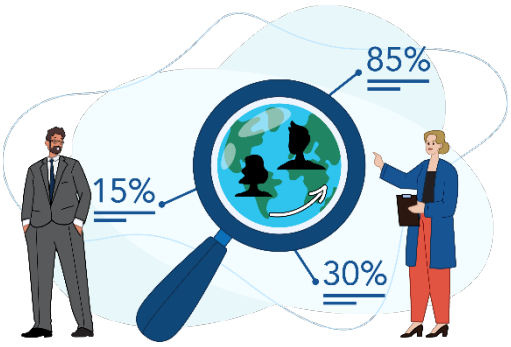
- **Informed consent** is an ongoing communication process that serves the ethical imperative of respect for persons.
    - **Consent forms** give potential participants the information they need to make an informed decision.
    - **Further consent discussions** allow participants to ask questions.
- **Participant-centered consent forms** help to recruit and retain participants — ultimately serving both participants and research teams!

### Key Takeaways:

- The **central ethical principles for protecting human research participants** are respect for persons, beneficence, and justice.
- **Informed consent ensures** potential participants have the information needed to make an informed decision about participation.
- **Common problems with consent forms** include unnecessary or overly complicated information, poor formatting, and non-participant-centered writing.
- **Participant-centered consent forms** provide the needed information in a way that's understandable, meaningful, and tailored to the participants.

Informed consent is a critically important and ongoing process of communicating respectfully with research participants. A well-written consent form provides potential participants with the necessary information about the study to make an informed decision about participation. Further consent discussions allow participants to ask questions and let researchers address any additional individualized informational needs. The effort we put into informed consent is not only an ethical imperative, in fact, recent research suggests that participant-centered consent forms help research teams recruit and retain participants. In this way, the effort ultimately serves both participants and research teams. Review this module's key takeaways before moving to the next module.

# Module 2: How Do I Use a Participant-Centered Approach?




## Module 2 Learning Objectives

**You will be able to:**

- Explain what makes consent forms meaningful for potential research participants.
- Use a participant-centered approach to provide context in consent forms.

After completing this training module, you will be able to explain what makes consent forms meaningful for potential research participants and use a participant-centered approach to provide context in consent forms. The participant-centered approach focuses on what information participants would want to have and how they'll interact with and react to consent forms. It emphasizes the importance of staying focused on the participants' perspectives and thinking about the impact and implications of the information you give them.

## What Is the Required Information?

**Consent forms must provide the information that a reasonable person would want to have in order to make an informed decision about participation, including (among others):**

- Purpose of the research.
- Reasonably foreseeable risks or discomforts.
- Expected duration of participation.

- Reasonably expected benefits.
- Procedures to be followed.

Learn more about the Common Rule's General Requirements for Informed Consent.

Per the Common Rule, consent forms must provide the information that a reasonable person would want to have in order to make an informed decision about participation. The regulations further specify what types of information to include, such as the purpose of the research, the expected duration of the subject's participation, the procedures to be followed, any reasonably foreseeable risks or discomforts, and any benefits that participants can reasonably expect. However, including the legally required information in consent forms is only one part of our task.

## Writing for the Participant

**How we explain the information is as important as the information itself.**

Use a **participant-centered approach** to:

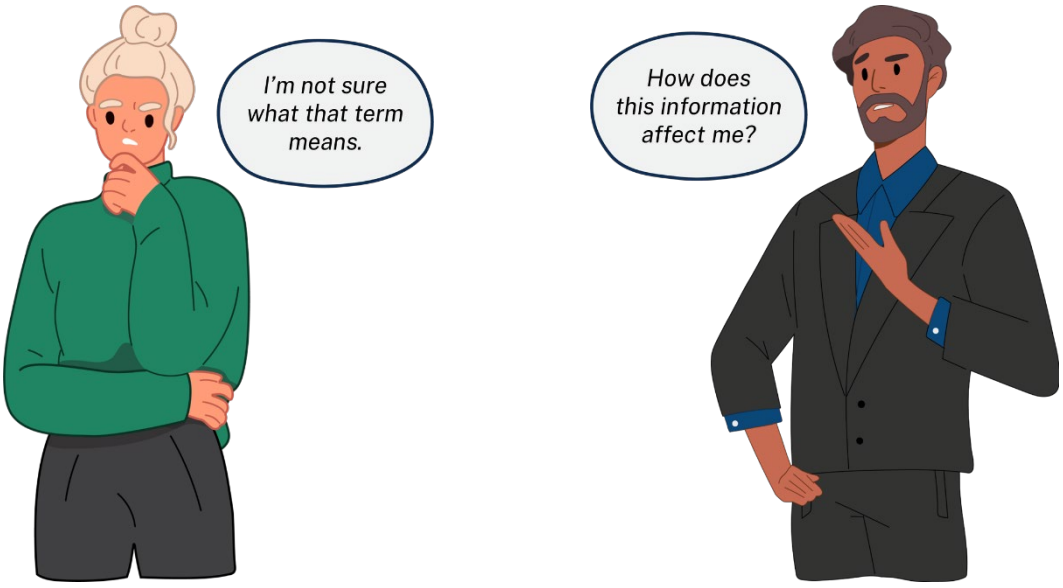
- Communicate in a way participants understand.
- Ensure participants have the information needed to give informed consent.
- Keep participants' perspectives and needs in mind.

In addition to including the required information, we also want to communicate it in a way that helps participants understand. How we explain the information is equally important to the information itself because if participants don't understand the information, they can't give informed consent. This is why we use a participant-centered approach to keep potential participants' perspectives and needs in mind when developing consent forms.

## What Is the Participant Perspective?

**Explaining research to potential participants using a participant-centered perspective helps avoid confusion and prioritizes the information participants care most about.**

It can help to get input from your intended participant population or representative advocacy groups to better understand their perspectives.




Within the research community, we're mostly familiar with explaining our research to peers and scientific reviewers. Explaining research to potential participants will require us to adopt a participant-centered perspective. Most research participants are not experts in scientific or medical concepts and may be unfamiliar with them. And, importantly, the information potential participants value might be different from the information researchers think is most important. For example, participants who lead a busy life may be much more concerned with how long the study visits and procedures will last rather than details on how the study procedures work. From their perspective, scientific details aren't usually as important and may be overwhelming or confusing. Getting input from a sample of individuals from the intended participant population or representative advocacy groups could help us better understand, identify, and present information about the research in a manner that may be most relevant and helpful to potential participants.

# Why the Participants' Perspectives Matter

Review the excerpts from consent forms where the content is not participant centered.

### Excerpt 1: Confusing list of risks

| Excerpt text: | What's the problem? |
|---|---|
| **Neurological Risks**<br>• Chronic nerve damage<br>• Psychological intolerance<br>• Stroke/transient ischemic attack<br>• Subdural, epidural hematoma<br>**Cardiac Risks**<br>• Arrhythmia<br>• Cardiac arrest<br>• Cardiac tamponade<br>• Low cardiac output state | This example could confuse potential participants and won't necessarily help them make an informed decision because it:<br>• Organizes risks by physiological systems, which may not be meaningful to readers.<br>• Uses specialized terms that would be unfamiliar to most readers.<br>• Omits further useful information, such as how serious or likely an occurrence would be. |

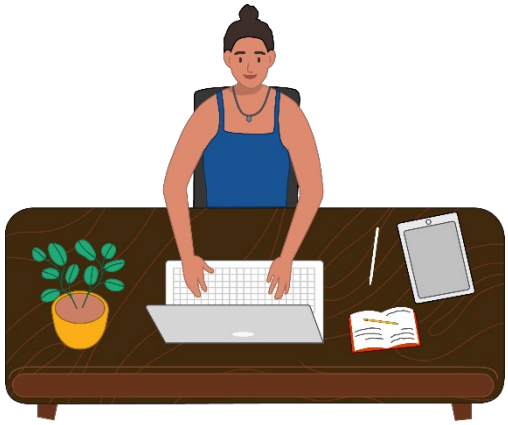
### Excerpt 2: Vague description of risks

| Excerpt text: | What's the problem? |
|---|---|
| Any research has some risks, which may include things that could make you feel unwell, uncomfortable, or could harm you. You might have adverse effects (side effects) related to the study drug while taking part in the study. These effects may be mild or serious. In some cases, these effects might be long lasting, or permanent, and may even be life-threatening. | In this example, the explanation of risks or discomforts needs to be more specific for it to be meaningful for participants.<br>For example, what exactly does "unwell" mean?<br>• If it means sleepy, dizzy, or experiencing double vision, what might that mean for a potential participant?<br>• If it means they could be unable to drive or operate machinery, it would be helpful to specify this since it could impact their everyday life. |

## Using a Participant-Centered Approach

**Keep the participants' perspectives in mind.**

- Frame, explain, and present information to help potential participants make informed decisions.
- Explain research concepts meaningfully.
- Fulfill ethical responsibility of informed consent.



These examples illustrate why it's so important to use a participant-centered approach when writing and editing consent forms. When we keep the research participants' perspectives in mind, we can frame, explain, and present information in ways that help potential participants understand and make informed decisions. Explaining complex research concepts meaningfully and in everyday language is an essential part of fulfilling our ethical responsibility related to informed consent.

## Providing Context Helps Participants Understand Information

**Context refers to how specific details relate to each other (or not).**

| | |
|---|---|
| **Why?** | • Context provides people with the setting or background of a situation and helps them understand how things may or may not be connected.<br>• Context helps people understand why information is significant.<br>• Context helps potential participants understand how information relates to them. |

Context refers to how specific details relate to each other or don't relate to each other — and should be considered separately. It provides people with the setting or background of a situation and helps them understand how things may or may not be connected. With context, people can understand why the information is significant and what it means within a larger situation. When consent forms include enough context, potential participants can better understand what the information means, how it relates to them, and why it's important. On the other hand, when context is missing, potential participants may misunderstand key details and might even miss those details entirely. Let's look at a few examples to see how incorporating context helps us write more meaningful consent forms that give potential participants the information they would want to have.

## Describing Randomization: Context Example 1

**"We will assign you to one of the two study groups by chance, like flipping a coin."**

This description is probably adequate for a study that **doesn't offer the potential for any direct benefits** because participants don't have much stake in the groups they are randomized to.

In consent forms, "randomization" is commonly explained with something like: "We will assign you to one of the two study groups by chance, like flipping a coin." This description is probably adequate for a study that doesn't offer the potential for any direct benefits because participants don't have much stake in the groups they are randomized to. For example, in a study that examines different methods to record peoples' reflexes while playing a video game, participation offers no direct benefits, and participants won't have a stake in which group they're assigned to, so this simple explanation is sufficient.

## Describing Randomization: Context Example 2

| | |
|---|---|
| **However:** | What about a **randomized cancer clinical trial** where one group will receive a promising new drug, while the other group will only receive the usual treatment?<br>That changes things. In this context, **participants have a stake** in which group they're assigned and may want to know more about the assignment. |
| **Solution?** | Clearly explain the **precise implications of randomization** for the participants. |

On the other hand, imagine a randomized cancer clinical trial studying a promising investigational drug. The researchers will randomly assign participants to one of two study groups. One group will receive the promising drug, while the other group will only receive the usual treatment. In this context, the situation is very different. Many people participate in cancer clinical trials because they want access to a promising drug that may help their condition. But neither they nor their doctors have a say in what group they're randomized to. This affects the desired outcome by significantly cutting the chance of them getting the study drug. This concept is very different from what participants are familiar with in clinical care, where their best interest and preference take precedence. In this context, it is important to clearly explain the precise implications of randomization for the participants.

## Activity 1: Thought Exercise

Pretend that you are a potential research participant in this cancer clinical trial. The trial randomizes participants into two study groups, Group A and Group B. Group A will receive the promising investigational drug. Group B will receive the usual treatment. **Review and select the statements about randomization that you think will impact your decision-making and should be included in the consent form.**

A. The researchers will randomly assign you to Group A or B.

B. A computer will do the randomization using a random number generator.

C. Your group assignment is not based on your preference.

D. You have an equal chance of being in either group.

E. Your doctor cannot decide which group you will be in.

F. We will not tell you which group you are in while you are in the study.

G. If you decide to participate, you should be willing to accept whichever group we assign you to.

Check answer to Activity 1: Thought Exercise

## Resource: Explanation of Randomization

**You can use this boilerplate explanation of randomization with blinded assignment in your own consent forms for similar studies.**

"We will assign you to 1 of the 2 study groups by chance, like flipping a coin [*if your study has more than 2 randomized groups, use "We will assign you to 1 of X study groups by chance, like drawing from a hat"].* Your group is not based on what you want or what seems best for you. You will have an equal chance *[or 1 in X chance determined according to the total number of groups in the study]* of being in either group. You will not be told which group you are in during the study. The study researchers also will not know which group you're in. So, if you agree to participate, you will need to be okay with being in either group and not knowing which group you're in."

Open the Randomization Boilerplate (PDF)

This example provides a good explanation for the common study design that incorporates randomization with a blinded assignment. You can use it in your own consent forms for studies like this. You can also download this document from Appendix B: Resource List.

## Drawing Distinctions

**Comparing and contrasting the information you give to potential participants provides helpful context.**

Many people make their decision to participate or not by weighing **how being in the study will make things different** from what they know or are familiar with.

One useful technique to provide helpful context is to "compare and contrast" the information you give to potential participants. Many clinical trial consent forms only provide information on the research procedures and interventions being studied, without referencing other alternatives, such as the usual care given outside of the research, or the care given to participants in the research study's control groups. Without that contextual information, potential participants have nothing to compare the research information to. When we ask people to make decisions about being in a research study, many will try to weigh how being in the research study will make things different for them, such as changes to the care they have been receiving or the care that they may normally receive.

## Drawing Distinctions: Example

This example compares and contrasts what would happen to one group versus another in a randomized trial studying two standards of care practices for treating scoliosis in children.

### What to expect if we *do* ask your child to wear a back brace for this study

It's possible that wearing a back brace could help slow the curving of your child's spine. This might help them avoid surgery. But wearing the back brace has some drawbacks:

- Your child might find it to be inconvenient or restrictive.
- The brace might be uncomfortable and could injure the skin or cause skin ulcers.
- Your child might feel stressed or embarrassed around others while wearing the brace.

It's also possible that wearing the brace will not help your child and that the curve in their spine will get worse before their backbone stops growing. In that case, your child could experience these drawbacks without gaining anything personally from this study. You or your child can decide to stop being in the study at any time.

### What to expect if we *don't* ask your child to wear a back brace for this study

Your child will not receive the help that a back brace might provide. But they will not have any of the discomfort and inconvenience that can come with wearing a brace.

It's possible that the curve in your child's spine could get worse before their backbone stops growing. But you can choose to remove your child from the study and seek treatment at any time. Common treatments for scoliosis recommended by doctors include observation, wearing a back brace, or possibly undergoing surgery.

## Activity 2: Thought Exercise

Pretend you are a potential research participant in this cancer clinical trial that randomizes participants into one of two groups. Group 1 will receive standard care. Group 2 will get the promising investigational drug being studied, Drug X. **Review and select the statements below that represent information you would want to have to make an informed decision about participation.**

A. The risks and discomfort associated with Drug X.

B. The degree to which foreseeable risks and discomforts from Drug X may be different from the risks and discomforts of standard care.

C. Any foreseeable problems with replacing the standard of care with Drug X alone.

D. The degree to which potential benefits from Drug X may be different from the benefits of standard care.

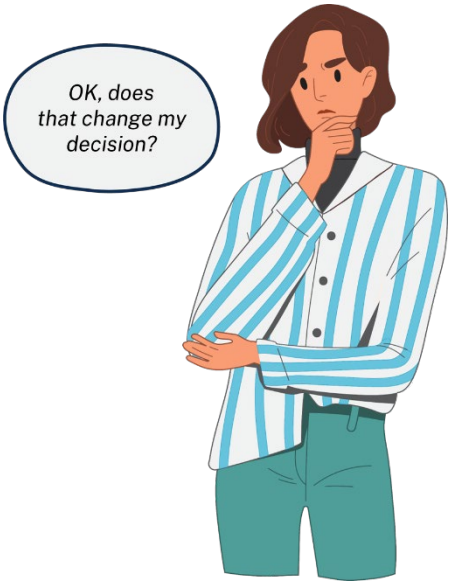
E. Detailed science on how Drug X might work.

Check answer to Activity 2: Thought Exercise

## Explaining Potential Impacts of Participation

**Consent forms may need to explain the research's potential impact on participants.**

**For example:** "If you decide to participate in this study, you may not be able to participate in similar studies in the future."



To help people make informed decisions about research participation, consent forms may need to explain the implications or potential impact of certain study activities or procedures. For example, participants who agree to be in a study that examines the effectiveness of a particular gene replacement procedure may not be eligible for a similar procedure in the future.

## Activity 3: Thought Exercise

Consider a study in which researchers ask participants to install an app on their phone that will send reminders for them to attend therapy sessions. The app will also deliver messages and conduct surveys to supplement the cognitive-behavioral therapy they receive for their mental health condition. **Select the statements below that represent information that should probably be included in the consent form.**

A. Potential costs for installing the app, receiving messages, and interacting on the app.

B. Information the app will collect and impacts on the privacy of the participant.

C. Description of the icon the participants will see when they receive a notification.

D. Who will have access to the data collected by the app and how that information will be used by these third parties.

E. How the collected information will be protected for confidentiality.

Check answer to Activity 3: Thought Exercise

## Module 2 Conclusion

**For a participant-centered approach:**

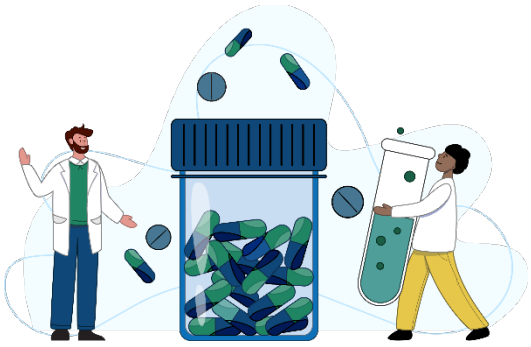
- Step away from a formal scientific writing style.
- Break down complex concepts.
- Provide contextual information.

**Key Takeaways:**

- **Context** refers to the relationship of different details — in consent forms, different contexts require different types of information and levels of detail.
- **Contextual information** makes consent forms meaningful and allows potential research participants to make an informed decision.
- **Using a patient-centered approach** provides context by showcasing specific information and how it relates to other important details, focusing on what participants want, and determining how they'll interact with and react to consent forms.

In a participant-centered approach, we step away from the more formal and scientific writing style used in the research community. Instead, our job is to break down complex concepts and to provide relevant contextual information to help potential participants understand. Writing consent forms with this participant-centered approach helps ensure that people have the necessary information they would want to have to make an informed decision about whether to participate in research. Review this module's key takeaways before moving to the next module.

# Module 3: How Can I Write Better Consent Forms?



## Module 3 Learning Objectives

**You will be able to:**

- Convey information clearly and concisely to potential participants.
- Refine your word choice for potential participants.
- Revise overly long, complex sentences.

After completing this training module, you will be able to convey information clearly and concisely to potential participants using techniques such as refining word choice and revising overly long, complex sentences. Using these strategies when writing consent forms helps people understand the information on their first read-through, without needing to guess what the content means.

# Section 1: Word Choice

## *Getting Started: Choosing Words Intentionally*

**Use words that people who aren't experts in research can easily read and understand.**

- Consider your audience's background, including their education and medical literacy.
- Use language they'll understand.
- Explain concepts clearly in simple terms.

In 2017, The Department of Education estimated that **52% of U.S. adults had low level literacy proficiency.**

Program for the International Assessment of Adult Competencies (PIAAC)

Choosing words intentionally means using words that people who aren't experts in research can easily read and understand. Our goal is to use words that improve clarity and avoid words that can cause confusion, which involves thinking about which words will best convey your intended meaning to potential participants. Always keep in mind that, although literacy rates vary widely, about half of U.S. adults read below a 6th grade level. General understanding of science and health topics also varies widely. Consider your audience's background, including their education and medical literacy, use language they'll understand, and explain concepts clearly in simple terms.

## *Use Words Your Audience Can Easily Understand*

**Use common, everyday words to improve understanding.**

- Instead of medical terms, use familiar words.
- Instead of research terms, use everyday language.

Think about times when you've read a complicated form or an article about an unfamiliar topic. **Isn't that experience made easier when the writer replaces specialized terms with everyday language?**

We can help potential participants understand consent forms by using common, everyday words. This means swapping medical terms for familiar words, such as using “kidney” instead of “renal.” Follow this rule even if it means using more words. For example, in everyday language, “birth control” is more familiar than “contraceptive.” It’s also important to replace specialized research terms with everyday language. Think about times when you’ve read a complicated form or an article about an unfamiliar topic. Isn’t that experience made easier when the writer replaces specialized terms with everyday language? Review the examples of medical and research terms that you could replace with simpler words.

### Example Medical Terms

| Medical Term | Suggested Alternatives |
|---|---|
| **anemia** | low red cell blood count |
| **bradycardia** | slow heartbeat |
| **carcinogenic** | cancer causing |
| **computed tomography** | CT scan |
| **contraceptive** | birth control |
| **hypertension** | high blood pressure |
| **imaging studies** | scans |
| **neuro-cognitive** | brain function |
| **Orally** | by mouth |
| **renal** | Kidney |
| **subcutaneous** | under the skin |

### Example Research Terms

| Research Term | Suggested Alternatives |
|---|---|
| **adjuvant treatment** | added treatment |
| **ameliorate** | improve or make (someone) feel better |
| **baseline** | before the research starts |
| **detrimental** | harmful or bad |
| **disclose** | give out, share |
| **intervention** | drug, procedure, activity, etc. (depending on context) |
| **PRN** | as needed |
| **protocol** | study plan, steps, activities |
| **randomize** | put into a group by chance |

## *Avoid Words with Multiple Meanings*

**Avoid words that are ambiguous or have multiple meanings. For example:**

- Biweekly: twice a week or once every two weeks?
- Poor: low income or low quality?
- Prevent: putting a stop to something or reducing the chance of something?
- Idiomatic expressions: "gold standard," “on the fence,” and “on the same page.”

Unless the intended meaning is unmistakable in context, avoid words that are ambiguous or have multiple meanings. For example, “biweekly” can mean either twice a week or once every two weeks. The word “poor” can mean low income but also low quality. In most contexts, “prevent” means “putting a stop to” something happening, but in a medical context, “prevent” often only means “reducing the chance of” something happening. So, for example, if a vaccine is only intended to reduce the chance of an infection occurring, then consent forms should make this clear and not use the word “prevent,” which might be misunderstood. Additionally, avoid idiomatic expressions, like "gold standard," “on the fence,” or “on the same page.” These non-literal expressions can be confusing, especially for non-native English speakers. Read the following examples of ambiguous or idiomatic words and phrases and their suggested alternatives.

## Example Ambiguous Terms

| Ambiguous Term | Suggested Alternatives |
|---|---|
| ***acute* could mean...** | new or recent |
| | sudden or urgent |
| ***biweekly* could mean...** | twice a week |
| | once every two weeks |
| ***instrument* could mean...** | survey tool, medical tool, measurement tool, etc. |
| | musical instrument |
| ***poor* could mean...** | low quality, faulty, or inadequate |
| | low income, impoverished |
| ***prevent* could mean...** | stop from happening |
| | lower the chance of |
| ***sensitive* could mean...** | confidential or private |
| | easily injured or hurt |
| | easily insulted |
| | uncomfortable, difficult, tense, financial, illegal (as in, a *sensitive* topic) |
| ***trauma* could mean...** | injury to the body |
| | emotional injury |
| | event that causes injury |

### Example Idiomatic Terms

| Idiomatic Term | Suggested Alternatives |
|---|---|
| **all clear** | allowed, given approval |
| **around the clock** | at all times, without stopping, day and night |
| **gold standard** | best, preferred, most reliable, etc. |
| **milestone** | important event, action, or achievement |
| **off the record** | private, confidential, not published, not official |
| **on the fence** | unsure, undecided |
| **on the same page** | agreed, have the same goals/understanding |
| **red flag** | sign that something is wrong |

## *Consider Negative Connotations*

**Avoid terms that might provoke negative emotions in common use.**

For example, in the medical field "chronic" means "long duration" (as in, chronic pain). But in common use, "chronic" can mean "very bad" or "never ending."

- Potential participants may consider labels like "mentally ill" and "manic depressive" offensive or disrespectful.
- Consider using person-first language instead — person-first language acknowledges that people who participate in research are more than just their diagnosis or medical condition.
    - "People who live with mental illness."
    - "People with bipolar disorder."

It's a good idea to avoid terms that might provoke negative emotions in common use. For example, the medical field commonly uses "chronic" to mean "long duration," as in chronic pain. But potential participants may perceive the word as implying unrelenting pain for their entire lives, which could be quite frightening. When considering negative connotations, be sure to think about terms that may be stigmatizing or dehumanizing. For example, the terms "mentally ill" and "manic depressive" are labels that people may consider offensive or disrespectful. Instead, consider using person-first language — such as "people who live with mental illness" or "people with bipolar disorder." This language acknowledges that people who participate in research are more than just their diagnosis or medical condition. Read the examples below and consider how potential participants are likely to understand the suggested possible alternatives more accurately and more positively than the original terms.

### Example Terms with Negative Connotations

| Term | Suggested Alternatives |
|---|---|
| **chemo-naïve** | participant who has not had chemotherapy before |
| **chronic** | long-lasting |
| **drug abuse** | substance use disorder |
| **drug addict** | someone with substance use disorder |
| **malignant** | cancerous |
| **manic-depressive** | individual with bipolar disorder |
| **mentally ill** | individual living with mental illness |
| **morbidly obese** | person who is very overweight |
| **opioid user** | person who uses opioids |
| **treatment-naive** | someone who has not taken this kind of medicine before |

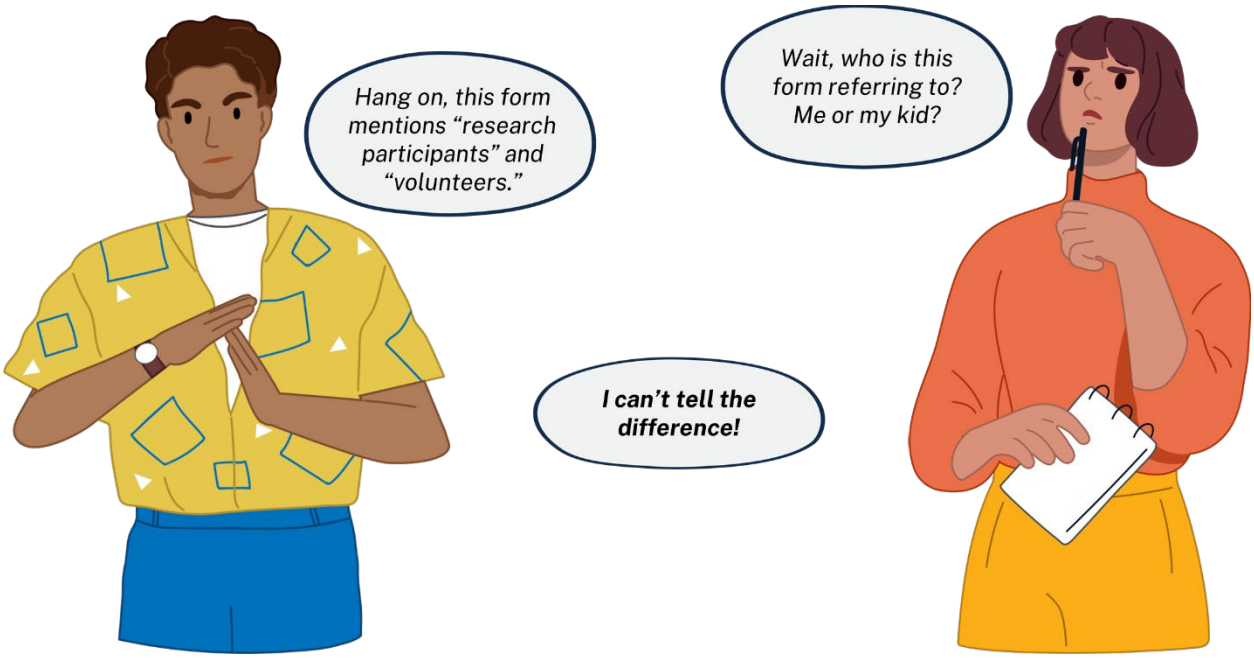
## *Be Specific About What You Mean*

**Provide information that is sufficiently specific.**


Provide information that is sufficiently specific. For example, stating that the study is trying to find out if a new drug works "better" or is "more effective" than the current treatments is too vague. What does "better" or "more effective" refer to specifically? Fewer side effects? Relief from symptoms? Total remission? A cancer patient might interpret "better" as curing the cancer, while a researcher might only mean that the drug could prolong the person's life by a few months or relieve some of the disease's symptoms. There's a huge difference, so don't leave potential participants guessing. Be clear and specific.

## *Use Terms Consistently*

**Once you choose a term, use it consistently.**




Using the same term for the same concept throughout a consent form will help ensure comprehension. Switching terms or using synonyms causes confusion — so once you choose a term, use it consistently. For example, if a consent form uses the term "research participants," don't use the term "volunteers" to refer to the same group later in the document. This applies to pronouns, too. For example, in consent forms for studies involving children, you should be consistent with how you use the term "you." If the audience includes parents as well as child participants, it would be confusing if the pronoun "you" is sometimes used to address the parent and sometimes the child in the same consent form.

## *Minimize Definitions*

**Using these strategies minimizes the need to define specialized terms.**

**But if you have to define a term:**

1. Do not assign a different meaning to a common word.
2. Define a word where you first use it, not at the beginning or end of the document; definitions operate best in context.
3. Don't define words you don't actually use in the document.

Using all these strategies helps minimize the need to define specialized terms in consent forms. But sometimes, using an unfamiliar word is unavoidable. When you must define a term, follow these rules to help boost reader comprehension: 1) Do not assign a different meaning to a common word. For example, avoid sentences like "For the purposes of this study, the word allergen refers only to poison ivy" because some readers will forget the new definition as they read. 2) Define a word where you first use it, not at the beginning or end of the document; definitions operate best in context. At the beginning of the document, potential participants haven't yet encountered the word, and, by the end of the document, they've probably already applied their own understanding of the word. And 3) Don't define words you don't actually use in the document.

## *Minimize Acronyms*

| How? | • Consider using a simplified name instead of an acronym. For example, after the first mention of a medical clinic with a long name, try calling it "the Clinic."<br>• If you need to use an acronym, **always define it the first time**. Consider spelling it out again later to help readers remember. |
|---|---|

Use as few acronyms as possible since they can be hard to remember and can confuse or overwhelm your readers. One alternative is to use a simplified name instead of an acronym. For example, if we're writing about a medical clinic with a long name, after the first use, we could refer to it simply as "the Clinic." If you must use an acronym, always define it the first time and consider whether you should spell it out again later to help readers remember it. In some cases, however, an acronym or abbreviation is preferred because it's more well-known than the full term - such as with "COVID" or "laser." Read the following list of acronyms and abbreviations that are more well-known than their full terms.

### List of Common Acronyms and Abbreviations

| Abbreviation/Acronym (preferred because of common usage) | What the Abbreviation/Acronym Stands For (avoid unless necessary |
|---|---|
| **COVID-19** | COronaVIrus Disease of 2019 |
| **CT (scan)** | computed tomography |
| **DNA** | deoxyribonucleic acid |
| **HIV** | human immunodeficiency virus infection/acquired immunodeficiency syndrome |
| **IQ** | intelligence quotient |
| **laser** | light amplification by stimulated emission of radiation |
| **MRI** | magnetic resonance imaging |
| **MRSA** | methicillin-resistant Staphylococcus aureus |
| **NSAID** | nonsteroidal anti-inflammatory drug |
| **REM (sleep)** | rapid eye movement |

# Section 2: Testing Readability

## *Readability Tests*

| | |
|---|---|
| **Definition** | **Readability tests assess how difficult text is to read and understand** using factors such as the lengths of sentences and words, the number of total words per sentence, and (sometimes) the vocabulary used. |
| **Drawbacks** | **These tests can't consider:**<br>• Contextual relevance of information.<br>• Meaning of the words used.<br>• Organization of the content.<br>• Formatting of the document. |

Readability tests are designed to assess how difficult text is to read and understand. Many readability tests use the lengths of sentences and words and the number of total words per sentence to calculate a readability score. Some compare the vocabulary used in the text to a list of common words. Different tests use different formulas and measure slightly different things. However, readability tests can't consider the contextual relevance of the information, the meaning of the words used, the organization of the content, or the formatting of the document — all factors that greatly influence understanding. So, while these scores can be helpful, they are not enough to decide if potential participants will be able to understand a consent form.

## *Using Readability Scores Thoughtfully*

**Readability scores can still be helpful tools during the revision process.**

- Run readability tests on individual sentences or paragraphs.
- If the score improves with each revision, the text is probably getting easier to understand.
- If the score indicates the sentence or paragraph is too difficult for most readers, it probably is.

However, readability scores can still be helpful tools during the revision process. After all, using shorter sentences and words usually does improve clarity. But rather than calculating readability scores based on your entire document, which may not provide an accurate picture, score individual sentences or paragraphs. In general, if the readability score of a sentence or paragraph improves with each revision, the text is probably getting easier to understand. And if the score indicates the sentence or paragraph is too difficult for most readers, it probably is. Read about different types of readability tests below.

Learn about and use all the tests described below

| Readability test | How it's calculated | Score output and interpretation notes |
|---|---|---|
| **Flesch Reading Ease** | Sentence length (words/sentence) and word complexity (syllables/word) | **From 1 (very confusing) to 100 (very easy)**<br>Compared to Flesch-Kincaid Grade Level, emphasizes the importance of short words (that is, long words lower the score more than long sentences). |
| **Flesch-Kincaid Grade Level** | Sentence length (words/sentence) and word complexity (syllables/word) | **US grade levels**<br>Compared to Flesch Reading Ease, emphasizes the importance of short sentences (that is, long sentences increase the score more than long words). |
| **Automated Readability Index** | Sentence length (words/sentence) and word complexity (characters/word) | **US grade level**<br>Unlike most tests, uses the number of characters rather than the number of syllables to measure word difficulty. |
| **Gunning Fog Index** | Sentence length (words/sentence) and word complexity (percentage of hard words) | **US grade level**<br>Defines words with three or more syllables as hard. |
| **New Dale-Chall Formula** | Sentence length (words/sentence) and word complexity (percentage of hard words) | **US grade level**<br>Defines words that aren't on a list of words familiar to most fourth graders as hard. |

# Section 3: Writing and Revising Sentences

## *Moving from Words to Sentences*

**Write sentences as intentionally as you select words.**

**Note:** Some of following examples use Flesch-Kincaid readability scores to compare the original sentences to their revisions. Remember, readability tests are useful, but **a "good" readability score does not necessarily mean a passage of text is understandable.**

In addition to choosing words intentionally, we also need to consider how the words are strung together. This section goes over some advice for writing sentences and analyzing and revising awkward sentences. Some of the examples include Flesch-Kincaid readability scores to compare the difference between the original examples and the revisions. Once again, remember that while readability tests are useful, a "good" readability score does not necessarily mean a passage of text is understandable.

## *Write Short, Simple Sentences*

- Consider limiting most sentences to one idea each.
- Break complex information into short sentences.
- Use lists to convert lengthy paragraphs to concise lines.
- Put the main idea of the sentence at the beginning of the sentence.

A sentence should typically express one idea. Shorter sentences convey complex information more efficiently than long sentences by breaking the information up into smaller pieces. Bulleted or numbered lists also help convert lengthy paragraphs into concise lines. In addition, the main idea of a sentence should come first — before any supplemental information or exceptions. That way, readers don't have to backtrack to understand what they've read. For example, if a sentence begins with something like "Except in the case of...," people may need to re-read the beginning of the sentence to understand the exception's relation to the rest of the sentence. Reversing the order of the information solves this problem. Read the following two examples of rewritten consent form language using shorter, more concise sentences.

### Example 1 Original

In this research, because the tooth is irreversibly damaged, you will receive root canal treatment after your tooth is anesthetized, and soft tissue called 'pulp' containing vessels and nerves in the center of the tooth will be extirpated with instrumentation and irrigation.

*Flesch Reading Ease: 21.2*
*Flesch-Kincaid Grade Level: 20.7 (college graduate and above)*

### Example 1 Rewrite

As part of this study, you will have a root canal to remove damaged areas of soft tissue at the center of your tooth. We will numb your tooth and then remove the tissue with water and dental tools.

*Flesch Reading Ease: 80.8*
*Flesch-Kincaid Grade Level: 6.8 (7th grade)*

### Example 2 Original

Unless you end your study participation early or your doctor determines that it's unsafe for you to continue participating, we expect that your active participation in the study will take place over approximately 12 weeks.

*Flesch Reading Ease: 16.6*
*Flesch-Kincaid Grade Level: 19.6 (college graduate and above)*

### Example 2 Rewrite

Your study activities will take place over about 12 weeks. The time may be shorter if you choose to leave the study early or if your doctor decides it's not safe for you to continue in the study.

*Flesch Reading Ease: 71.8*
*Flesch-Kincaid Grade Level: 8 (8th grade)*

## *Write in a Conversational Style*

**Write as if you were speaking to simplify text.**

> "If you came to the determination that it was better for you to leave the study phase, you would be given an invitation to participate in a follow-up phase."

The original sentence above uses complex sentence structure and multiple verb forms that we're much less likely to use when speaking. Notice how the rewrite below simplifies the sentence by using a more conversational and natural style.

> "If you decide to stop being in this part of the study, we'll invite you to join the follow-up part."

To help simplify text in consent forms, it's helpful to write in a conversational style — as if you were speaking. Consider the following sentence from a study consent form: "If you came to the determination that it was better for you to leave the study phase, you would be given an invitation to participate in a follow-up phase." In this example, we see complex sentence structure and multiple verb forms that we're much less likely to use when speaking. We can make the sentence much simpler by thinking about how we might say it out loud: "If you decide to stop being in this part of the study, we'll invite you to join the follow-up part."

## *Use Active Voice*

**Use active voice to simplify text and keep the tone conversational.**

| What? | **In active voice, the subject of the sentence is doing an action instead of being acted upon.**<br>In passive voice, the doer of the action is not the subject of the sentence and may not be identified at all |
|---|---|

One of the best ways to simplify text and write in a conversational style is to use active voice. In active voice, the subject of the sentence is doing an action instead of being acted upon. In passive voice, the doer of the action is not the subject of the sentence and may not be identified at all. For example, in the passive sentence "The sample will be collected," the subject of the sentence is the sample, not the people performing the action. The more concise, active way to write the sentence would be "A study team nurse will collect your sample." It's important to note that, in the research community, we often use passive voice in scientific writing to convey a sense of objectivity. That's why it's usually not a good idea to copy text written for scientific reviewers and re-use it in consent forms. The examples below show more comparisons between the passive and active versions of sentences you might see in a consent form.

| Original (Passive) | Rewrite (Active) |
|---|---|
| The sample will be collected. | A study team nurse will collect your sample. |
| A summary of the study's outcomes will be sent to the study participants. | We will send you a summary of the results. |
| Additional information will be communicated to you by a member of your study team. | A member of your study team will give you more information. |
| You will be asked questions about your health. | We will ask you questions about your health. |

**Avoid copying and re-using text written for scientific reviewers in consent forms!**

## *What to Do When You Get Stuck*

- Work through each section paragraph by paragraph and sentence by sentence.
- Read your document aloud to ensure that you're using short sentences, active voice, and a conversational style.
- Try stepping away from the keyboard and just speaking your thoughts.

- Ask someone who is unfamiliar with your project to read your draft consent, such as a colleague, friend, or a community volunteer who is representative of your audience.

Revising consent forms is not an easy task. Be patient and work through each section paragraph by paragraph and sentence by sentence. Although it may seem awkward, reading your document aloud is probably the best way to ensure that you're using short sentences, active voice, and a conversational style. Taking a break if you get stuck can also be helpful. Try stepping away from the keyboard and just speaking your thoughts. An important and well-tested strategy to help you spot confusing text is to ask someone who is unfamiliar with your project to read your draft consent, such as a colleague, friend, or — better still — a community volunteer who is representative of your audience. You may be surprised by these unfamiliar readers' different impressions or by which information they identify as confusing. Some research projects even have patient partners involved in the writing of consent forms.

## *Activity 1: Identify Problem Areas*

**Read the original excerpt and the suggested rewrite. Consider the differences and determine why these changes were made.**

### Original Excerpt

This study may require participation lasting up to 72 weeks, during which time you will be asked to complete 4 data collection study visits either in the research clinic setting or on the phone. During the data collection study visits, you will be asked to complete questionnaires about your sociodemographic characteristics, health, physical activity, cognitive activity, and other health behaviors.

*Flesch Reading Ease: 23 (very difficult)*
*Flesch-Kincaid Grade Level: 17.55 (college graduate)*

### Suggested Rewrite

You will be in the study for up to 72 weeks. In that time, we will ask you to complete 4 surveys either by phone or in person at our research clinic. The surveys will ask about your life, overall health, brain function, physical activity, and other activities that can affect your health.

*Flesch Reading Ease: 72 (fairly easy)*
*Flesch-Kincaid Grade Level: 7.55 (8th grade)*

Check suggested responses for Activity 1: Identify Problem Areas

## *Activity 2: Rewrite A Consent Form Passage*

**Read the consent form excerpt below. Using the strategies from this module, how would you rewrite it to be more participant centered?**

### Original Excerpt

If you are interested in participating in this research study, we will have to first make sure that it is safe for you to be a study participant. To do this, we will ask you some questions and have you complete a questionnaire about your medical condition, which includes telling us about your symptoms and all the current medicines you are taking. We will also do a physical exam on you and test your urine for the presence of certain drugs, and because parts of this study may be harmful to a growing fetus, if there is a possibility that you could be pregnant, we will also do urine pregnancy tests to avoid this risk.

*Flesch Reading Ease: 46 (difficult)*
*Flesch-Kincaid Grade Level: 16.39 (college graduate)*

*Test readability!*

Check suggested response for Activity 2: Rewrite A Consent Form Passage

## Module 3 Conclusion

**As you write or review consent forms:**

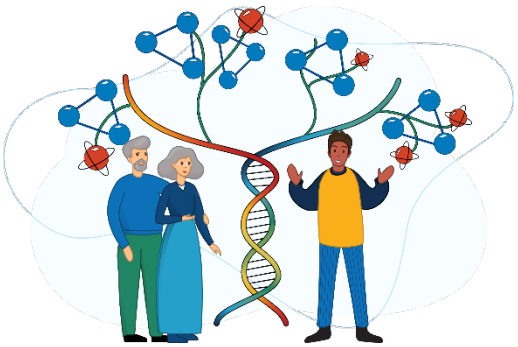
- Focus on clear and concise communication.
- Choose familiar, everyday words without multiple meanings or negative connotations.
- Use a conversational tone and use active voice whenever possible.

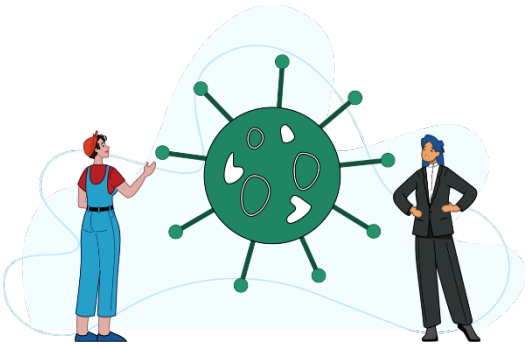
**Key Takeaways:**

- **Choose words intentionally** by using words your audience can easily read and understand — avoid specialized terms, words with multiple meanings, and words with negative connotations.
- **Minimize confusion** by limiting the number of definitions and acronyms.
- **Increase readability** by writing short, simple sentences in active voice.
- **Revise your consent form** — don't hesitate to read it aloud or ask for feedback.

As you write or review consent forms, focus on clear and concise communication. At the word-choice level, choose familiar, everyday words without multiple meanings or negative connotations. At the sentence level, use a conversational tone and use active voice whenever possible. Whether you're the writer or the reviewer, the guidelines in this module can help make your consent forms easier to understand and, hopefully, more effective. Review this module's key takeaways before moving to the next module.

# Module 4: How Can I Organize Information in Consent Forms?





## Module 4 Learning Objectives

**You will be able to:**

- Organize consent forms around a narrative that helps potential participants locate and understand critical information.
- Write useful section headings and present the information in a meaningful order.

After completing this training module, you will be able to organize consent forms around a narrative that helps potential participants locate and understand critical information. You will also be able to write useful section headings and present the information in a meaningful order.

## How Do People Read Consent Forms?

| | |
|---|---|
| **Situation** | • Most people find it hard to stay engaged with long documents full of unfamiliar information.<br>• People are more likely to skim over a document if the relevance of the information isn't clear to them. |
| **Solution** | • Organize information in a way that clearly shows potential participants **how the information is relevant** to their decision to participate or not. |

Organizing the information in consent forms with the audience in mind is the first step toward keeping readers engaged. Many consent forms are long documents full of information unfamiliar to most people, making it hard to stay engaged. Even when the writing is simple and clear, people are more likely to skim over a document if the relevance of the information isn't clear to them. So, it's helpful to organize information in a way that clearly shows potential participants how the information is relevant to their decision to participate or not.

## Providing Key Information First

The Common Rule requires consent forms to begin with a "key information" section.

| | |
|---|---|
| **Why?** | • To focus potential participants' attention on the main reasons why they may or may not want to participate.<br>• To serve as a framework that helps potential participants process the rest of the document's more detailed content. |

**Tips:**

- Include hyperlinks or page references to help readers navigate to details later in the form.
- For some simple research, the key information may already include most of the information that needs to be in the consent form.

The Common Rule requires consent forms to begin with a presentation of "key information." The purpose of this section is to focus potential participants' attention on the main reasons why they may or may not want to participate in the research. We can include lengthy details and supplemental information later in the consent form. This way, the key information section can serve as a framework that helps potential participants process the rest of the document's more detailed content. You can also put hyperlinks or page references within the key information to help readers navigate to additional details provided later in the form. For simple research that doesn't require a lot of information, the entire consent form may only be a few pages long, with the key information section making up most of or even all the content.

## What Is Key Information?

Think about your potential participants' perspectives and motivations. What information is key to helping them decide to participate or not?

**In most cases, key information would include:**

- Statement saying that participation is voluntary.
- Concise description of what the research study is about.
- Description of what will happen to participants.
- The main risks and benefits.
- Any appropriate alternative procedures or courses of treatment.

When identifying which information is key to helping people decide to participate or not, one approach could involve considering our potential participants' perspectives and motivations. In most cases, key information would include a statement saying that participation is voluntary, a concise description of what the research study is about, and a description of what will happen to participants, what the main risks and benefits are, and any appropriate alternative procedures or courses of treatment. The key information section does not need to include all the basic and additional elements required by the Common Rule. You can include the additional required information as well as any other details in the rest of the consent form.

## What Else Might Be Key Information?

**Key information can sometimes include supplemental information *beyond* the elements required by the regulations.**

| When? | If the supplemental information is likely to be important to potential participants' decision about research participation, then it could belong in the key information section. |
|---|---|

**Example:**

For a study with potential risks to people beyond those participating in the research (like family members), you may want to highlight that possibility in the key information.

> Key information can sometimes include supplemental information beyond the elements required by the regulations, if the supplemental information is likely to be important to potential participants' decision about research participation. For example, for a study where research participants receive radioactive interventions, there could be potential risks to people not participating in the research, such as family members. You might decide the key information section should highlight this possibility to alert participants to the risks their research participation could pose to others.

## Selecting Key Information: Example Study

> Read the synopsis of a clinical study below. When you're ready to continue, we'll consider several categories of information and determine whether we should put that type of information into the key information section of this study's consent form.

**Clinical Study Synopsis**

This clinical study is trying to find out if watching an image change slightly while walking can improve the step-to-step adjustments made by seniors to keep their balance. The study will ask adults over 65 with a history of falls to participate.

Participants will walk comfortably on a treadmill under supervision while looking at an image in front of them. They'll do this two times on separate days for 20 minutes each time. The first time, they'll walk while viewing a still image (control). The second time, they'll walk with the image moving slightly side to side (intervention).

## Selecting Key Information: Walk-through

Review the explanations below for where we could put this type of information in a consent form for the above clinical study.

**Note:** This is NOT a complete list of information that could be included in the key information section.

| Type of information | Belongs in key information section? | Explanation and notes |
|---|---|---|
| **Brief description of study purpose** | Yes, likely belongs in the key information section | This tells the subject what the study is about.<br>**Tip:** If there are additional details that may help better explain the study, put these in the rest of the consent form. |
| **Brief description of study activities** | Yes, likely belongs in the key information section. | This information tells people what will happen in a concise way without overloading them with details that may be confusing.<br>**Tip:** More detailed explanation about the procedures can go in the rest of the consent form. |
| **Detailed information about each of the two visits** | No, does not usually belong in the key information section. | This type of detailed information can be included later in the consent form. |
| **Legal disclaimers** | No, does not usually belong in the key information section. | This information can be provided in the rest of the consent form. |
| **Time involvement information** | Yes, likely belongs in the key information section. | This study involves seniors whose participation in the activities may require help from caregivers.<br>Concrete information about time involvement may be key information impacting the decision to participate. |

# Activity 1: Identifying Key Information Content

**Imagine a research study examining two discharge options for people who have been treated on an inpatient basis for substance abuse disorder. Decide whether the following six statements could belong in the key information section.**

### Statement 1

If you are in Group 2, you will receive standard care. This does not include a predetermined plan. For this hospital, standard care may include referrals to speak with someone about opioid use.

A. Yes, likely belongs in the key information section.

B. No, does not usually belong in the key information section.

### Statement 2

If you are in Group 1, you will receive a plan for substance use treatment including medications that can help reduce drinking and opioid use after you leave the hospital.

A. Yes, likely belongs in the key information section.

B. No, does not usually belong in the key information section.

### Statement 3

We will use a computer algorithm to do the randomization to the study groups.

A. Yes, likely belongs in the key information section.

B. No, does not usually belong in the key information section.

### Statement 4

This is a randomized research study. That means we will assign you to one of two study groups (Group 1 and Group 2) by chance, like flipping a coin.

A. Yes, likely belongs in the key information section.

B. No, does not usually belong in the key information section.

### Statement 5

A team of physicians, psychologists, and clinicians at the JM Institute for Mental Health developed this plan.

A. Yes, likely belongs in the key information section.

B. No, does not usually belong in the key information section.

### Statement 6

In this study we want to find out if providing a plan of follow-up treatment for people treated for substance abuse when they leave inpatient care will make it less likely for relapses to happen.

A. Yes, likely belongs in the key information section.

B. No, does not usually belong in the key information section.

Check suggested responses for Activity 1: Identifying Key Information Content

## Example Key Information Section

Select the link below to open one possible example of a part of a key information section. You can also download this document from Appendix B: Resource List.

Open the Example Key Information Section (PDF)

## Organize Ideas into a Coherent Narrative

**How you organize information can affect how well readers understand.**

- Create a coherent narrative that potential participants can easily follow.
- Use a logical structure that clearly shows how different pieces of information are related.

How you organize information in the key information section and the rest of the form could affect how well readers can understand the consent form in general. A well-organized consent form uses a coherent narrative that potential participants can easily follow and has a logical structure that clearly shows how different pieces of information are related. Deciding what information to include, how much, and where to include it is another important part of effectively organizing information in consent forms.

## Concise and Relevant Rewrite Example

Read the following excerpt from a key information section. Then, read the updated version. The updated version rewrites the content into an understandable, coherent, and logical format.

### Original Excerpt

**Does this study involve genetic testing?**

Yes, this study involves BDNF Val66Met polymorphism and APOE-ε4 candidate gene analysis with DNA extraction from whole-blood samples. The BDNF Val66Met polymorphism affects how BDNF, a protein related to the brain, is secreted into the blood. The APOE-ε4 allele is a genetic risk factor for Alzheimer's dementia. These genetic factors may be related to how interventions, such as lifestyle behavioral intervention or drugs, affect memory.

### Updated Excerpt

**Does this study involve genetic testing?**

Yes, we will use your blood samples from this study to do genetic testing for the risk of developing Alzheimer's dementia. These tests may help us learn about how genetic factors might affect the prevention and treatment of dementia.

The rewrite answers the question succinctly, providing the most relevant information. More specific information about genes and interventions for dementia may be included in the rest of the consent form as needed.

## Consent Form Narrative

**Introduce information in a way that follows how potential participants are likely to process the information.**

They should be able to understand information and put it in context as it is introduced, **without having to reread past sections or read ahead.**

The consent form narrative should introduce information in a way that follows how potential participants are likely to process the information. Readers should be able to understand information and put it in context as it is introduced, without having to reread past sections or read ahead. As a general example, it would make sense to explain what the study is about and what participants will need to do before explaining the potential risks and burdens of participation. You can adopt this narrative strategy throughout the consent form.

## Logical Narrative Rewrite Example

Read the following excerpt on risks of a procedure. Then, read the updated version. The updated version rewrites the content into a logical narrative.

### Original Excerpt

**What are the risks of a lumbar puncture?**

Although rare, it is possible that you may have an allergic reaction to the local anesthetic (lidocaine l%) used for the lumbar puncture. This would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist). Potential but rare risks of lumbar puncture include infection, damage to nerves in your back and bleeding into the spinal fluid space. The risk of these is very small. A common risk includes headaches which can be severe.

**Updated Excerpt**

**What are the risks of a lumbar puncture?**

Having a lumbar puncture poses a few risks that you should know about. Headaches, some severe, are the most common. Other risks are rare, which means they only affect a small portion of people. They include:

- Infection
- Damage to the nerves in your back
- Bleeding around your spine
- Swelling and a rash caused by an allergic reaction to the numbing medicine.
    - Please tell us if you have ever had a bad reaction to numbing medicine before — for example, at the dentist.

The rewrite reorganizes the information to better answer the question posed by the section heading. More common risks are presented before rarer ones.

## Activity 2: Creating a Logical Narrative in Plain Language

**Read the following statements about what will happen to participants in this example study. Create a logical narrative by reordering the statements.**

1) **Statement 1:** The intervention will take place every day over 2 weeks.
2) **Statement 2:** Before starting the intervention, you will have an MRI scan at the research clinic.
3) **Statement 3:** During the 2-week intervention period, you will come to the research clinic at the same time each day.
4) **Statement 4:** The study intervention involves electrical stimulation of the skin near the pain site using electrodes like EKG electrodes.
5) **Statement 5:** After the 2-weeks of the intervention, you will have two more MRI scans 6 weeks apart.

Check suggested responses for Activity 2: Creating a Logical Narrative in Plain Language

## Separate Ideas into Sections

| | |
|---|---|
| **What?** | Organizing information into small sections keeps readers from feeling overwhelmed by too much information. |
| **How?** | • Address one general topic and divide the details up into short paragraphs, lists, tables, etc.<br>• Stick to the point, avoid irrelevant details, and minimize unnecessary repetition. |

Organizing information into small sections is usually helpful to the reader. A section should address one general topic, such as the purpose of the study or what activities the study will involve. Within each section, we can then divide the details up into short paragraphs, lists, tables, and so on. It's important to stick to the point, avoid irrelevant details, and minimize unnecessary repetition. Remember, even if the audience understands every word we use, they can still be overwhelmed by too much information.

## Create Useful Section Descriptions

**Contextualize section headings by presenting them as questions potential participants may ask about participation.**

| Common section heading | Heading rewritten as question |
|---|---|
| Procedures | What will happen if I participate? |
| Purpose | What is this study about? |

Section headings guide readers through a document and tell them what information they'll find in each section. A good way to contextualize section headings in a consent form is to present them as questions potential participants may ask about participation. For example, the heading "Procedures" doesn't tell a potential participant how the section relates to them. On the other hand, a heading like "What will happen if I participate?" tells them how the information given in that section is relevant to them.

## Activity 3: Rewriting Headings

**Match the following typical consent form headings with their more helpful rewrites.**

| Typical Headings | Suggested Rewrites |
|---|---|
| 1) Purpose | A) What will happen if I decide to be in this study? |
| 2) Invitation to Participate | B) Why are you asking me to be in this study? |
| 3) Procedures | C) What are my other options if I decide not to be in this study? |
| 4) Benefits | D) Could being in this study benefit me? |
| 5) Alternatives | E) What is this research study about? |

Check answer to Activity 3: Rewriting Headings

## Where Does Other Information Go?

**Additional information and details beyond key information can go in the rest of the consent form.**

**Tips:**

- Build a logical narrative.
- Break information into sections.
- Use headings that clarify the relevance of each section.
- Use links or page references to connect content from the key information section to the rest of the consent form.

**Potential section headings *after* the key information section:**

- More about this study's purpose.
- More about the risks and burdens of being in this study.
- What are my other options if I decide not to participate?
- Will you pay me to participate in this study?
- What if I'm injured due to my participation in this study?
- Who can I contact if I have questions?

Additional information and details that do not belong to the key information section can go in the rest of the consent form. This will also include any elements of informed consent that the Common Rule requires that are not already fully addressed within the key information section. Consider following the same strategies of building a logical narrative and breaking information into sections. You may use headings that clarify the relevance of each section, such as the ones above. As previously mentioned, you can use links or page references to connect content from the key information section to the rest of the consent form.

## Are There Ways to Shorten Consent Forms?

- Minimize repetition unless it will help your readers' understanding.
    - Consider being selective about the level of detail to include.
    - Too many logistical details can distract someone from the information they need!

**Some details only become really relevant after a person decides to participate. Consider providing those details in a supplemental document for actual participants.**

Usually there's no need to repeat information found in the key information section in the body of the consent form unless it helps with the audience's understanding of the content. Typically, minimizing unnecessary repetition makes the consent form shorter and more engaging. Separately, consider being selective about the level of detail to include in the consent form overall. Too many logistical details can distract someone from the information they need to make an informed decision about participation. Some details may not be as relevant until after a person decides to participate in the research, so one idea is to consider whether these can be provided in a supplemental document for actual participants.

## Module 4 Conclusion

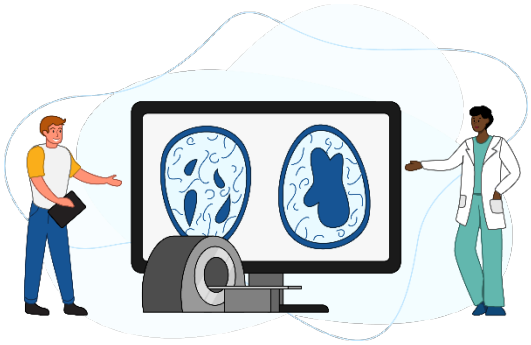
- Begin most consent forms with a **key information section**, which can:
    - Communicate the main reasons why the reader may or may not want to participate in the study.
    - Work as a framework to help the reader navigate the rest of the document.
- Organize consent forms around a logical narrative.
- Use meaningful section headings.

**Key Takeaways:**

- The **key information section** should communicate the main reasons why someone might or might not want to participate, could help facilitate discussions, and aid potential participants make sense of the details in the rest of the consent form.
- A **logical narrative** introduces information in a way that makes sense to potential participants and meets their needs and priorities.
- **Section headings** that are clear and specific help readers understand the consent form and locate relevant information.

Typically, consent forms begin with a key information section. This section could fulfill two functions. First, it should communicate the main reasons why the reader may or may not want to participate in the study. Second, it could work as a framework to help the reader navigate the rest of the document's more detailed content. Organizing the consent form around a logical narrative could help potential participants find and understand the information. Meaningful section headings could also help them quickly identify what each part of the form is about. Review the key takeaways before moving to the next module.

# Module 5: How Can I Design Consent Forms?



## Module 5 Learning Objectives

**You will be able to:**

- Explain how readers look for a visual hierarchy.
- Explain the best ways to help them navigate a document visually.

The participant-centered approach also applies to how we format consent forms. After completing this training module, you will be able to explain how readers look for a visual hierarchy and the best ways to help them navigate a document visually. This module will discuss the use of color, graphic elements, and visual representations of numbers, which can all improve the readability of documents when used effectively.

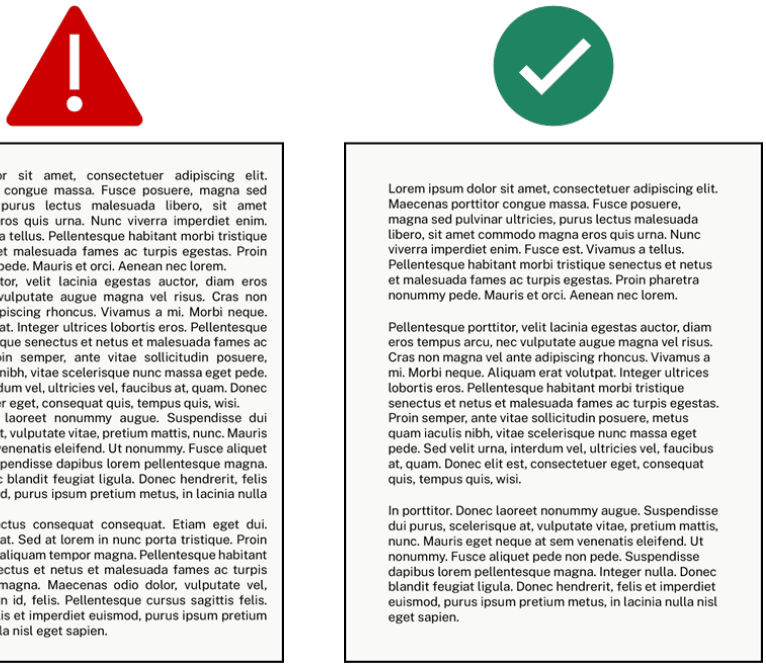
## What Are the Common Formatting Mistakes in Consent Forms?

Some formatting issues are made with the intention of using fewer pages or saving space. These issues include narrow page margins, minimal white space, text that is too small to read easily, and lengthy, dense paragraphs. Although we don't want to have very long consent forms, the solution isn't to squeeze as much content as possible onto each page. Other common issues include misuse of lists and overuse of formatting for emphasis, such as italicizing or bolding text unnecessarily. Lists and emphasized text can help potential participants identify important information, but misuse and overuse have the opposite effect.

**Review the before and after examples for each of the common mistakes below.**

Note that these examples use meaningless placeholder text to put the focus completely on the layouts.

## Narrow page margins and minimal white space



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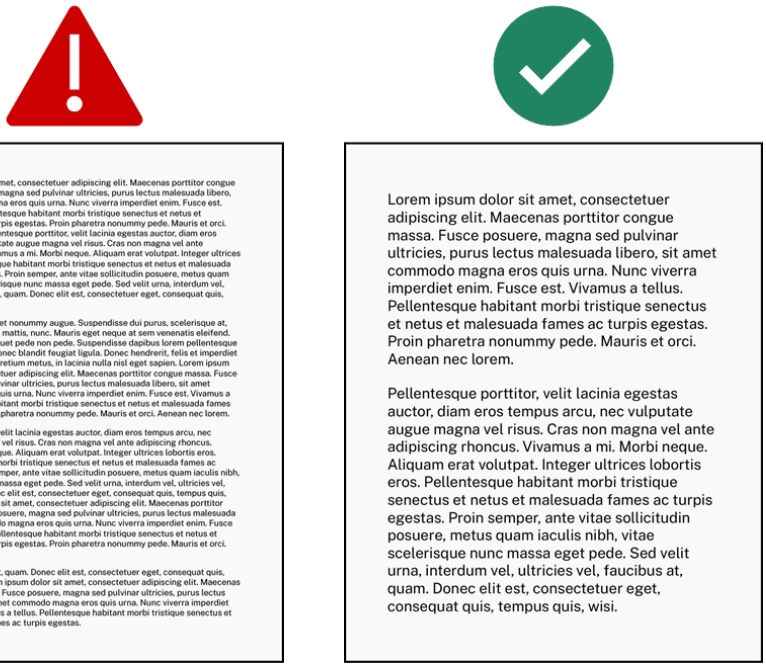
## Text that is too small to read easily



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## Lengthy, dense paragraphs

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## Misuse of lists

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### Misuse/overuse of formatting for emphasis

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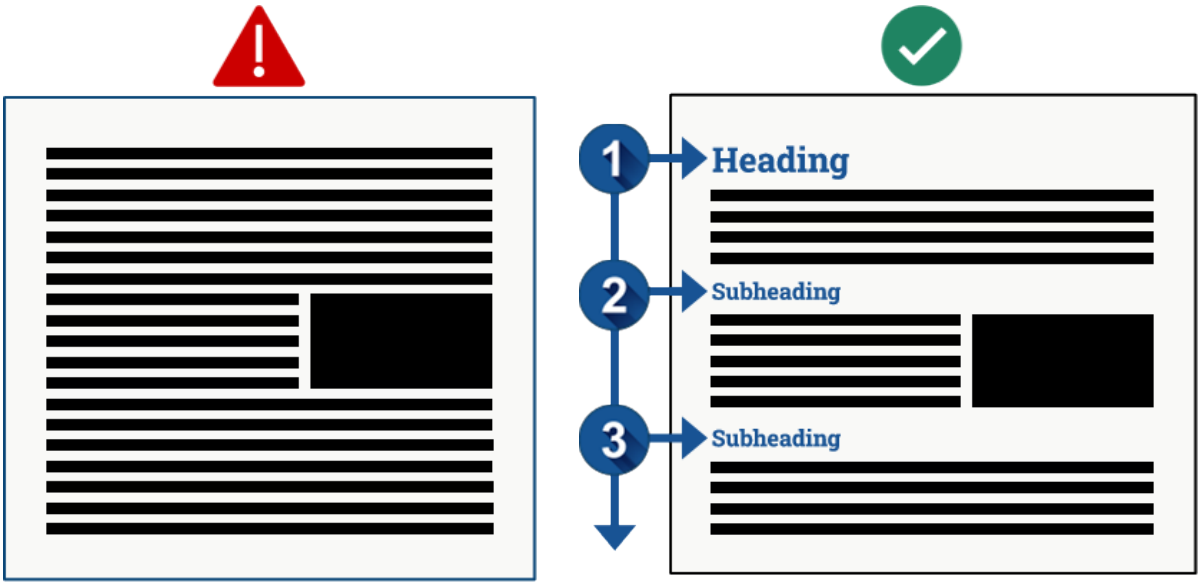
## What Is a Visual Hierarchy?

| What? | The way readers look at a document to **determine the importance** of information and **recognize relationships** between information. |
|---|---|

**Formatting mistakes can affect the visual hierarchy in a way that confuses or misleads readers.**

Graphic design skills aren't required to avoid, identify, or correct formatting issues. All you need is an awareness of visual hierarchy. Visual hierarchy refers to the way readers look at a document, determine the relative importance of information on a page, and recognize relationships between that information. Formatting issues affect the visual hierarchy in a way that can confuse or mislead readers. The following pages provide practical ways to build an accurate visual hierarchy in consent forms.

## Draw Attention to Important Information



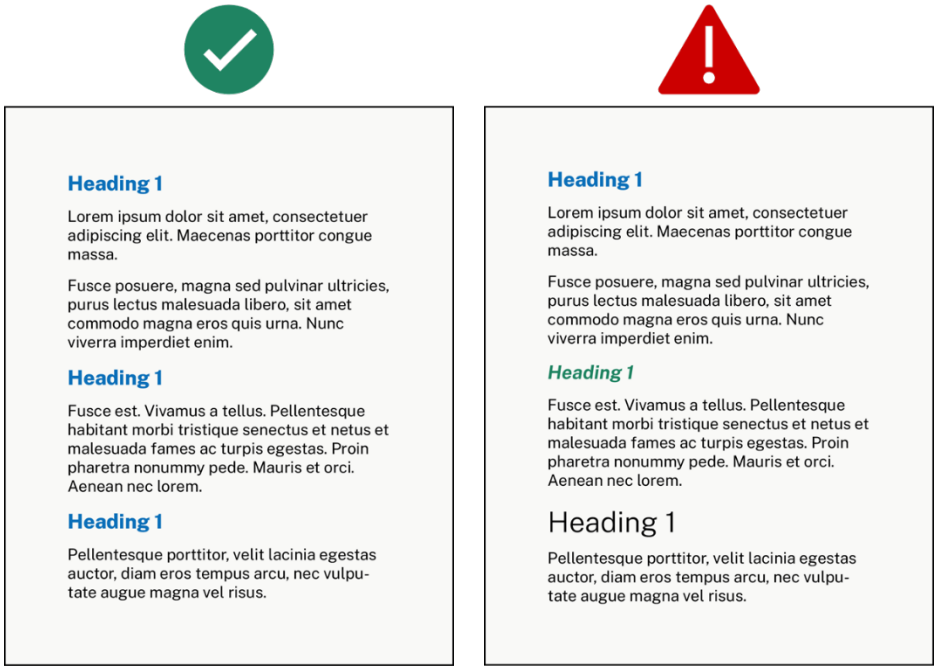

**Tips:**

- Use contrast, such as large text or bright colors, to draw the eye.
- The stronger the contrast, the more effective it is.
- Make headings and subheadings obvious (larger size, different color, etc.).

It's common for readers to scan the left side of a document and skip over anything that doesn't immediately look meaningful. Usually, the most different visual elements on a page catch a reader's attention first, such as the largest text or the brightest color. Take advantage of this tendency by organizing your consent forms into short, clearly labeled sections. Use prominent section headings to draw the eye, and clearly indicate each section's purpose to improve the odds that potential participants identify content as meaningful to them.

# Draw Connections Between Content: Repetition

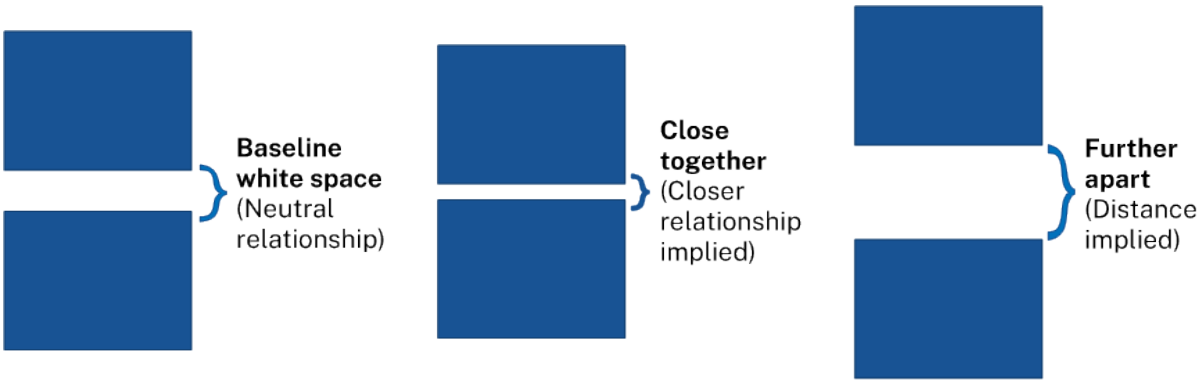
**Use repetitive visual clues to help readers group and organize elements in a document.**




Readers subconsciously use repetitive visual clues to group and organize elements in a document. For example, if every level 1 section heading is formatted the same way, readers automatically understand that those sections are “equal” to one another in the visual hierarchy. The key here is to use this type of repetition thoughtfully and to keep the patterns consistent. Inconsistent font sizes or heading levels used out of order could misdirect potential participants into connecting unrelated content or placing too much or too little importance on information.

## Draw Connections Between Content: Placement

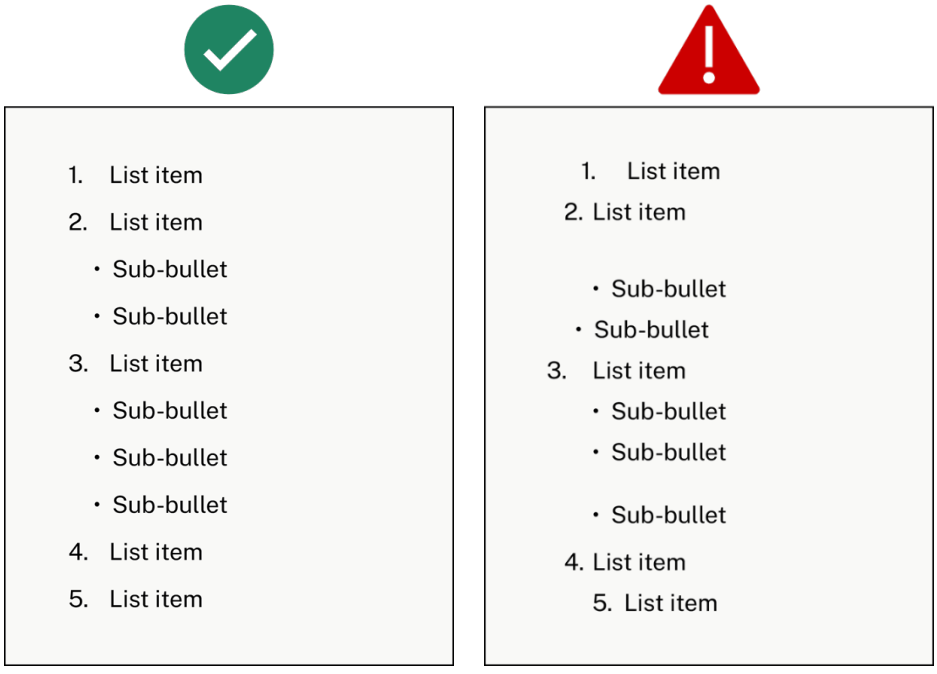
**You can use content placement to help convey meaning by embracing white space.**




Visual elements that are similarly placed on the page are interpreted as being related in the visual hierarchy. The best way to use content placement to help convey meaning is to embrace white space. A "baseline" amount of white space inserted throughout the document helps readers intuitively understand what it means if two visual elements are closer together than others, or further apart.

## Draw Connections Between Content: Placement (cont.)

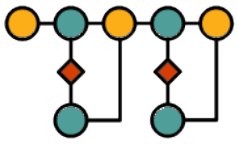
**Placement is most often a problem in lists, where content can seem to be grouped arbitrarily and the relationships between bullets may be uncertain.**



In consent forms, placement is most often a problem in lists, where content can seem to be grouped arbitrarily and the relationships between bullets may be uncertain. Items in a list are placed together, so they should strongly relate to one another. However, it's not uncommon to see consent forms with large amounts of information formatted as lists without a clear reason why. Lists with inconsistent spacing, which obscures the relationships between the items, are also common. Additionally, misaligned list bullets or numbers can confuse potential participants into thinking something is different about the misaligned text.

## Use Graphic Elements

| Why? | **Graphics can:**<br>• Add interest.<br>• Highlight important information.<br>• Group related information.<br>• Communicate information and concepts more quickly than long paragraphs or lists. |
|---|---|




Graphics, such as diagrams, bubbles, illustrations, and tables add visual interest, highlight important information, and group related information together. Some concepts are faster and easier to communicate visually, and there are many situations where these types of elements can aid potential participants' understanding. For example, flowcharts can be a more effective way to illustrate different stages of a study than a long paragraph. In many cases, long lists work better formatted as tables.

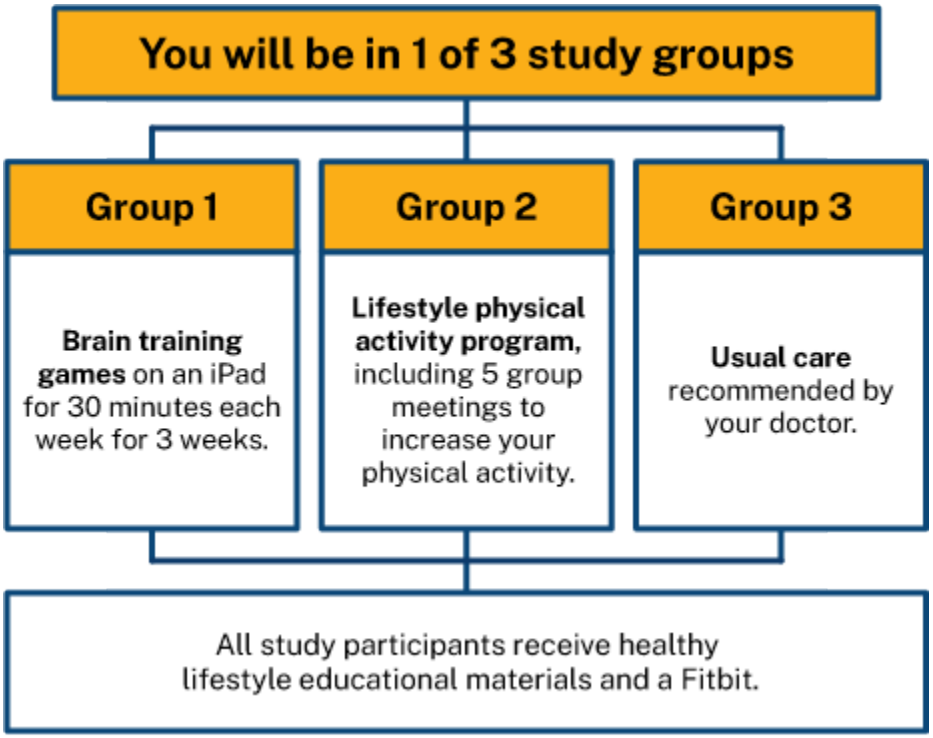
## Example: Converting a Paragraph to a Flowchart

The example paragraph below describes the different groups in a study, but the information is very densely packed. It's the sort of paragraph that's very easy for the eye to skip over.

**Original excerpt:**

If eligible for the study, you will be randomized (assigned by chance) to one of the following 3 groups: 1) A brain training program that consists of 3 weekly 30-minute sessions of brain training games on an iPad; 2) A lifestyle physical activity program that consists of individualized goal setting and 5 group meetings aimed at increasing your physical activity; or 3) Usual care, which is whatever your doctor recommends. All study participants will receive healthy lifestyle educational materials and a Fitbit.

The flowchart below organizes the same information into a much more reader-friendly visual that may complement the text description or even replace it at times.



## Inserting Graphic Elements: Color

**When using color graphics, be aware:**

- There are an estimated 300 million people in the world with color vision deficiency or color blindness.
    - Red-green color blindness is the most common type of color deficiency.
    - 1 in 12 men are color blind, compared to only 1 in 200 women.

**Avoid using color alone to convey meaning.**

**Example:** Red text often signals critical information or a warning. If you use red to draw potential participants' attention to something, make sure to convey the same meaning in a different way as well.

This is a critically important sentence. However, that sentence's only difference from the rest of the text is the red color, which not all readers will be able to distinguish. It's easy for those readers to unknowingly miss it.

**Warning: This is a critically important sentence.** Bolding the sentence and putting the word "warning" before the sentence also draws the reader's attention, including any who can't see the red color.

**Warning: This is a critically important sentence.** Other ways to draw attention include increasing the size of important information or adding an icon to indicate the importance.

There are a few things to keep in mind when using color graphics, however. First, there are an estimated 300 million people in the world with color vision deficiency or color blindness. To make a document more accessible, avoid using color alone to convey meaning. For example, red text commonly signals critical information or a warning. However, the most common type of color blindness makes it hard to tell the difference between red and green. It's still appropriate to use the color red to draw potential participants' attention, but always ensure that something in addition to color is there to convey the same meaning. It could be as simple as starting the sentence with the word "Warning" in bold text or inserting a descriptive icon.

## Inserting Graphic Elements: Tables

**Keep tables simple, uncluttered, and easy to read.**

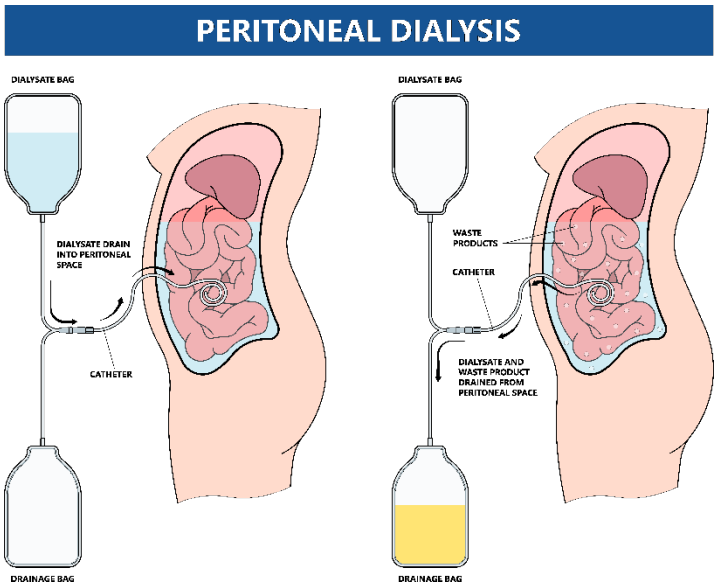
| Study activities | Screen | Baseline | Month 6 | Month 12 |
|---|---|---|---|---|
| Medical history | ✓ | | | |
| Medication review | ✓ | ✓ | ✓ | ✓ |
| Physical exam | ✓ | | ✓ | ✓ |
| Vital signs and weight measurement | ✓ | ✓ | ✓ | ✓ |
| Fasting blood collection | | ✓ | ✓ | ✓ |
| Adverse event monitoring | ✓ | ✓ | ✓ | ✓ |
| EKG | | ✓ | ✓ | ✓ |

Second, graphics should aid understanding, so keep them as simple and as clear as possible. For example, tables should be easy to read and understand quickly. White space is very important in tables to keep the information from becoming too cluttered to easily understand. Clearly differentiate column and row headers from the rest of the table content. Consider using banded rows, where alternating rows are different colors, to make the rows easier to read. Using dark-colored text on light backgrounds and light-colored text on dark backgrounds also makes text easier to read.

## Inserting Graphic Elements: Pictures

### How?

- Use content that is meaningful and easy to understand.
- Schematics, abstract, and graphic symbols should be made accessible.
- Place the images near the relevant content.

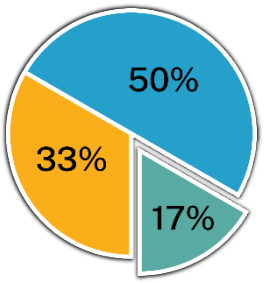


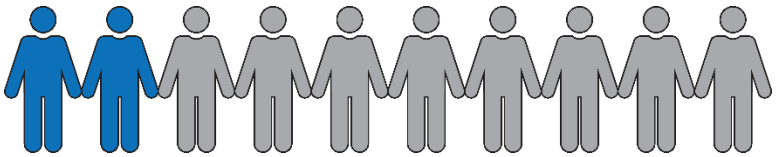

Diagrams and schematics should be clearly labeled. Put pictures immediately before or after the relevant content in the document so that potential participants can easily understand what the image refers to.

## Inserting Graphic Elements: Visual Representations of Numbers

**Many people have trouble with numerical concepts.**

- Use the simplest form possible.
- Help your audience visualize concepts.



Lastly, many people have trouble understanding numerical concepts, so always express these in their simplest form. Where possible, help potential participants visualize concepts. For example, text describing percentages can be confusing, but when displayed as a pie chart, the same information is easy to understand. Additionally, it's easier for readers to understand what 20% of people mean by visualizing 10 people with 2 highlighted.

## Module 5 Conclusion

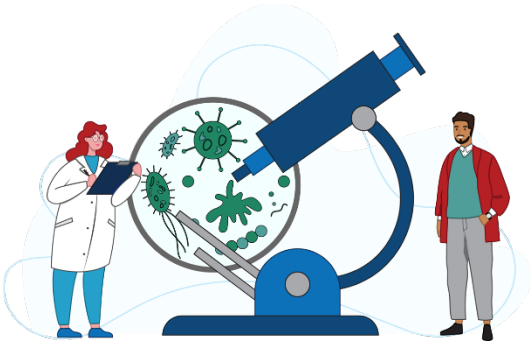
- Use design elements to improve readability and comprehension.
    - Keep your approach participant centered.
    - Embrace the philosophy that less is more!

**Key Takeaways:**

- **Clear, simple formatting** helps readers to quickly locate important information.
- **Contrast** draws attention to important information.
- **Repeated elements** and **variations in spacing** help readers understand connections between content.
- **Diagrams, illustrations, and tables** add visual interest, highlight important information, and group related information together.

The main goal of any document's design is to improve readability and boost comprehension. You don't need graphic design skills to do that. In fact, a very simple document with a clear visual hierarchy can be just as effective as one with a more complex layout. Keep your approach participant centered and embrace the philosophy that less is more. Not all consent forms need diagrams, tables, or other visual elements, and any that you do include should make the document simpler and easier to understand. Review the key takeaways before moving on to the final module.

# Module 6: Wrap-Up and Final Activity



## What Have You Learned?

Creating, designing, and reviewing consent forms using a **participant-centered approach**:

- Helps participants understand the content.
- Anticipates their needs by highlighting content relevant to them.
- Uses visual cues and a logical narrative to convey information clearly and concisely.

During the previous modules, you learned strategies for creating, designing, and reviewing consent forms using a participant-centered approach. To quickly recap, a participant-centered approach could help participants understand the content by anticipating their needs and highlighting the information most relevant to them. Consent forms could use visual cues and a logical narrative to clearly and concisely convey information to potential participants.

# Final Activity: Putting Everything Together

**Use strategies from the training to revise sections of a consent form.**

1) Read the study description below.

2) Then, make choices for the study consent form related to context, organization, writing, and design.

3) Evaluate what you've learned and continue to apply that knowledge to consent forms in the future!

For this training's final activity, you'll use what you've learned to revise sections of a consent form. Each of the following exercises will present two or more options for you to choose between. These choices relate to the principal strategies we've covered in this training: context, organization, writing, and design. There's never just one correct way to revise a consent form, but we hope you'll use this activity to evaluate what you've learned from the training and continue to apply that knowledge to consent forms in the future.

# Final Activity: Information on the Study

Before continuing, read the study description below. Think about the potential participants for this study and consider the types of information they would most want to know. When you're ready, continue to the first exercise.

### Study Description

This study will test whether or not receiving investigational DRUG X after chemotherapy and radiation could allow patients with metastatic CANCER Z to live longer.

In this study, half of the patients will receive DRUG X and the other half will receive a placebo by random assignment.

This study aims to determine whether the addition of DRUG X allows people with metastatic CANCER Z to live longer than those receiving chemotherapy and radiation alone.

## Exercise 1: Decide What to Include

**Which of the below information would most likely belong in the key information section for this study? (Select all applicable)**

A) “We’re doing this study to find out if receiving investigational Drug X following chemotherapy and radiation could allow people with metastatic Cancer Z to live longer than those receiving chemotherapy and radiation alone.”

B) “A computer will assign you by chance to treatment groups in the study.”

C) "You may not want to be in this study because you will only have half the chance of trying out Drug X."

D) “A computer will do the randomization assignment using a random number generator.”

E) “You may not want to be in this study because you will not be able to choose your treatment group and you will not know if you’re receiving Drug X or the placebo.”

Check answer to Exercise 1: Decide What to Include

## Exercise 2: Explain Concepts with Context for Participants

**Which of the below explanations of randomization and blinding is most appropriate for potential participants of this study?**

A) We will assign you to 1 of the 2 study groups by chance, like flipping a coin. An algorithm generated by a computer will assign you using a random number generator.

B) We will assign you to 1 of the 2 study groups by chance, like flipping a coin. Your group is not based on what you want or what seems best for you. You will have an equal chance of being in either group. You will not be told which group you are in during the study. So, if you agree to participate, you will need to be okay with being in either group and not knowing which group you’re in.

Check answer to Exercise 2: Explain Concepts with Context for Participants

## Exercise 3: Select the Clearest Option

**Which of the descriptions of a placebo below would likely be most easily understood by potential participants of this investigational drug study?**

A) Although it is physically indistinguishable from DRUG X, the placebo is an inert substance and will have neither detrimental nor beneficial effects.

B) The placebo is a pill that looks like DRUG X but has no effect.

C) The placebo looks like DRUG X but does not contain any active medicinal ingredients with efficacy.

Check answer to Exercise 3: Select the Clearest Option

## Exercise 4: Select the Clearest Option

**Which of the descriptions of this study's risks would likely be most easily understood by potential participants?**

A) Risks may include fatigue, transverse myelitis, tachycardia, pyrexia, brachial plexopathy, pneumonia, and pulmonary fibrosis.

B) Risks may include tiredness; lower body weakness, numbness, or paralysis; rapid heartbeat; fever; arm weakness or paralysis; lung infection; and scarring in your lungs.

C) **Serious risks may include:**

- Arm weakness or paralysis
- Lower body weakness, numbness, or paralysis
- Lung infection
- Scarring in your lungs

**Less serious risks may include:**

- Tiredness
- Fever
- Rapid heartbeat

Check answer to Exercise 4: Select the Clearest Option

## Exercise 5: Select the Clearest Option

**Which of the descriptions of how the researchers will use participant data would likely be most easily understood by potential participants?**

A) If at any point, you decide to withdraw from the study, then the data already collected by the researchers will continue to be kept and used for the purposes of the study, but no new data will be collected about you.

B) If you leave the study, we will keep your collected data for use in the study, but we won't collect any more data about you.

Check answer to Exercise 5: Select the Clearest Option

## Exercise 6: Select Section Headings

**Which of the lists of section headings would be most informative for potential participants?**

**A) List A:**

- What is the research study about?
- Why are you asking me to be in this study?
- What will happen if I decide to be in this study?
- What are the risks of being in this study?
- Could being in this study benefit me?
- What are my other choices if I decide not to be in this study?

**B) List B:**

- Purpose
- Study Eligibility
- Research Procedures
- Risks
- Benefits
- Alternatives to Participation

Check answer to Exercise 6: Select Section Headings

# Exercise 7: Make Design Choices

**Which of the design options below is most likely to help potential participants understand the information?**

A)

**Section Heading**

Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas porttitor congue massa.

Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim.

**Section Heading**

Fusce est. Vivamus a tellus. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas.

Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.

**Section Heading**

Pellentesque porttitor, velit lacinia egestas auctor, diam eros tempus arcu, nec vulputate augue magna vel risus.

B)

Section Heading

Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas porttitor congue massa.

Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim.

Section Heading

Fusce est. Vivamus a tellus. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas.

Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.

Section Heading

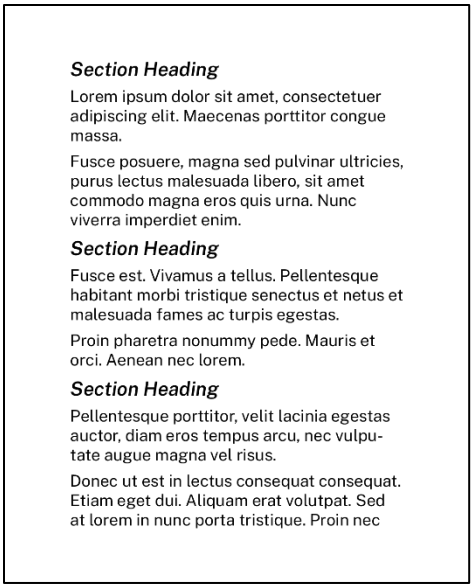
Pellentesque porttitor, velit lacinia egestas auctor, diam eros tempus arcu, nec vulputate augue magna vel risus.

Donec ut est in lectus consequat consequat. Etiam eget dui. Aliquam erat volutpat. Sed at lorem in nunc porta tristique. Proin nec augue.

Section Heading

Quisque aliquam tempor magna. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Nunc ac magna. Maecenas odio dolor, vulptate vel, auctor ac, accumsan id, felis.

C)



*Section Heading*

Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas porttitor congue massa.

Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim.

*Section Heading*

Fusce est. Vivamus a tellus. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas.

Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.

*Section Heading*

Pellentesque porttitor, velit lacinia egestas auctor, diam eros tempus arcu, nec vulputate augue magna vel risus.

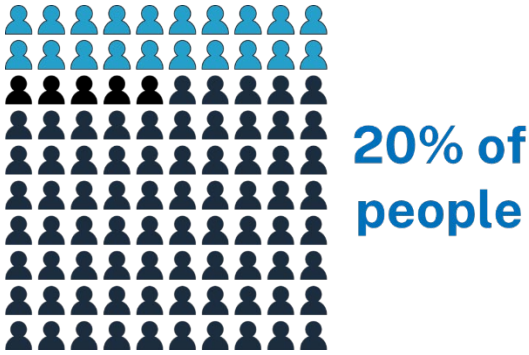
Donec ut est in lectus consequat consequat. Etiam eget dui. Aliquam erat volutpat. Sed at lorem in nunc porta tristique. Proin nec

Check answer to Exercise 7: Make Design Choices

## Exercise 8: Make Design Choices

**Which of the design options below is most likely to help potential participants understand the information?**

A)




B)


Check answer to Exercise 8: Make Design Choices

## Training Resources

Before we conclude, please open and save the documents below to use for reference in the future. You can also download these documents from Appendix B: Resource List.

- Participant-Centered Informed Consent Resource List (PDF): This document contains all the resources from the Resources tab of the online version of the Participant-Centered Informed Consent Training.
- Checklist of Strategies for Writing and Reviewing Consent Forms (PDF): OHRP's consent form checklist based on this training.

**You can use these documents for future reference!**

## What Comes Next?

**Apply the knowledge from this training to the consent forms you write or revise in the future and continue to hone your skills!**

**Want to push your consent forms even further?** Consider adopting more inclusive language and presenting consent forms using alternative media (illustrations, video, electronic tablets, etc.) to facilitate accessibility.

We hope you'll apply the knowledge from this training to the consent forms you write or revise in the future. The skills needed to provide information in a way that's understandable, meaningful, and tailored to the participants require practice and are honed over time. In addition to the strategies discussed in this training, you can also consider presenting consent form information using alternative media, such as illustrations, video, and electronic tablets, to meet the goals of improving clarity and increasing prospective participants' understanding of information to make informed decisions.

# Appendix A: Answer Guide

## Module 2 Activities

### *Activity 1: Thought Exercise*

**Correct answers: A, C, D, E, F, G**

All the statements are relevant *except* Option B: A computer will do the randomization using a random number generator. The method of randomization is usually not as relevant to potential participants.

Return to Module 2, Activity 1

### *Activity 2: Thought Exercise*

**Correct answers: A, B, C, D**

All the statements are relevant *except* Option E: Detailed science on how Drug X might work. In-depth scientific details about Drug X are unlikely to impact a potential participant's decision-making.

Return to Module 2, Activity 2

### *Activity 3: Thought Exercise*

**Correct answers: A, B, D, E**

All the statements are relevant *except* Option C: Description of the icon the participants will see when they receive a notification. At this point, participants do not need to know what the notification icon will look like on their phone.

Return to Module 2, Activity 3

# Module 3 Activities

## *Activity 1: Identify Problem Areas*

### Suggested Responses

1) **Overly long first sentence:** The rewrite splits the first sentence into two shorter sentences.

2) **Non-conversational tone:** The rewrite changes the first sentence to be more conversational.

3) **Passive voice:** The rewrite converts the passive voice to active voice ("you will be asked" to "we will ask you" or "the surveys will ask").

4) **Unfamiliar and specialized words:** The rewrite uses more common words.

   - "Data collection study visits" becomes "surveys."
   - "Sociodemographic characteristics" becomes "your life."
   - "Cognitive activity" becomes "brain function."
   - "Health behaviors" becomes "activities that can affect your health."

Return to Module 3, Activity 1

## *Activity 2: Rewrite A Consent Form Passage*

### Suggested Response

If you would like to be in this study, the first step is to make sure it is safe for you. To do this:

- We will ask you some questions to learn about your medical condition, your symptoms, and the medicines you take.
- We will do a physical exam and test your urine for the presence of certain drugs.
- If there is a chance that you could be pregnant, we will do a urine pregnancy test. We need to confirm that you are not pregnant because parts of this study may be harmful to a growing fetus.

*Flesch Reading Ease: 79 (fairly easy)*
*Flesch-Kincaid Grade Level: 7.06 (7th grade)*

Return to Module 3, Activity 2

# Module 4 Activities

## *Activity 1: Identifying Key Information Content*

**Statement 1:** In this study we want to find out if providing a plan of follow-up treatment for people treated for substance abuse when they leave inpatient care will make it less likely for relapses to happen.

> **Yes, likely belongs in the key information section.** This information is about what the researchers are trying to learn and could belong in the key information section.

**Statement 2:** A team of physicians, psychologists, and clinicians at the JM Institute for Mental Health developed this plan.

> **No, does not usually belong in the key information section.** This information may be helpful but is generally unlikely to be key to a person's decision about being in the study or not.

**Statement 3:** This is a randomized research study. That means we will assign you to one of two study groups (Group 1 and Group 2) by chance, like flipping a coin.

> **Yes, likely belongs in the key information section.** This information on study design could affect the kind of care the person receives and their decision to participate. This could belong in the key information section.

**Statement 4:** We will use a computer algorithm to do the randomization to the study groups.

> **No, does not usually belong in the key information section.** This technical description on how the randomization is done is unlikely to be key information affecting one's decision to participate.

**Statement 5:** If you are in Group 1, you will receive a plan for substance use treatment including medications that can help reduce drinking and opioid use after you leave the hospital.

> **Yes, likely belongs in the key information section.** This information with specifics on what will happen to participants assigned to Group 1 could belong in the key information section.

**Statement 6:** If you are in Group 2, you will receive standard care. This does not include a predetermined plan. For this hospital, standard care may include referrals to speak with someone about opioid use.

> **Yes, likely belongs in the key information section.** This information with specifics on what will happen to participants assigned to Group 2 could belong in the key information section.

Return to Module 4, Activity 1

## *Activity 2: Creating a Logical Narrative in Plain Language*

**Suggested re-ordering of statements:**

1) **Statement 4:** The study intervention involves electrical stimulation of the skin near the pain site using electrodes like EKG electrodes.
2) **Statement 1:** The intervention will take place every day over 2 weeks.
3) **Statement 2:** Before starting the intervention, you will have an MRI scan at the research clinic.
4) **Statement 3:** During the 2-week intervention period, you will come to the research clinic at the same time each day.
5) **Statement 5:** After the 2-weeks of the intervention, you will have two more MRI scans 6 weeks apart.

Return to Module 4, Activity 2

## *Activity 3: Rewriting Headings*

| Common section heading | Heading rewritten as question |
|---|---|
| 1) Purpose | E) What is this research study about? |
| 2) Invitation to Participate | B) Why are you asking me to be in this study? |
| 3) Procedures | A) What will happen if I decide to be in this study? |
| 4) Benefits | D) Could being in this study benefit me? |
| 5) Alternatives | C) What are my other options if I decide not to be in this study? |

Return to Module 4, Activity 3

# Module 6 Final Activity

## *Exercise 1: Decide What to Include*

**Correct answers: A, C, D, E**

The study purpose and information about the treatment groups and likelihood of receiving Drug X most likely belong in the key information section. How the randomization is actually done probably does not need to be in the key information.

Return to Module 6, Exercise 1

## *Exercise 2: Explain Concepts with Context for Participants*

**Correct answer: B**

For this study, the more in-depth explanation is appropriate because potential participants have a stake in their group assignment.

Return to Module 6, Exercise 2

## *Exercise 3: Select the Clearest Option*

**Correct answer: B**

The clearest option is the one without specialized terms (“active medicinal ingredients”) or uncommon words (“indistinguishable,” “inert,” “efficacy,” and so on).

Return to Module 6, Exercise 3

## *Exercise 4: Select the Clearest Option*

**Correct answer: C**

The clearest option uses the common rather than the medical term for each risk and provides context by separating the risks into serious and less serious categories.

Return to Module 6, Exercise 4

## *Exercise 5: Select the Clearest Option*

**Correct answer: B**

The clearer sentence avoids the use of passive voice and uses a more natural, conversational tone.

Return to Module 6, Exercise 5

## *Exercise 6: Select Section Headings*

**Correct answer: A**

The “question” section headings immediately tell potential participants how that section is relevant to them. The “topic” headings are more formal, and although they are commonly used, they are often too vague or abstract to be helpful to potential participants.

Return to Module 6, Exercise 6

## *Exercise 7: Make Design Choices*

**Correct answer: A**

Option A is the easiest to understand because it has wide margins, plenty of white space, and strong contrast between headings and body text. Option C isn’t bad, but the contrast isn’t as strong.

Return to Module 6, Exercise 7

## *Exercise 8: Make Design Choices*

**Correct answer: B**

Both options visualize the same information, but Option B presents it in the simplest form.

Return to Module 6, Exercise 8

# Appendix B: Resource List

Participant-Centered Informed Consent Resource List (PDF): This document contains all the resources from the Resources tab of the online version of the Participant-Centered Informed Consent Training.

Boilerplate Explanation of Randomization with Blinded (PDF): OHRP's example of an explanation of randomization which can be used in consent forms for similar studies.

Example Key Information Section (PDF): OHRP's example of part of a key information section with annotations explaining some of the writing and design decisions.

Checklist of Strategies for Writing and Reviewing Consent Forms (PDF): OHRP's consent form checklist based on this training.