Module 4: Informed Consent Communication

Introduction

Welcome to the fourth module in the Social and Behavioral Research Best Practices for Clinical Research course. Here we'll cover the informed consent process, its elements, and how this process helps to protect your participants, as well as your study's integrity.

Before we get started, let's hear from Ken, a research coordinator who will share how he prepared for his own informed consent process in a recently completed study.…

Ken's First Steps

We were preparing for a study that examined the effects of specific nutrients on processes like cognitive performance, alertness, and mood. Participants were going to be asked to keep food journals, take surveys, and perform cognitive and physical tests.

I was excited to get started! Our protocol had been finalized by the P.I. and the study team, and we were ready to develop informed consent procedures and the form for participants.

Writing an Informed Consent Document

Creating the informed consent document was pretty time-consuming. Study procedures had to be described, all the risks and benefits had to be laid out in full, and I had to anticipate any other questions the participants' might have before I even met them. It was a lot of work

Non-English Speakers

I was kind of nervous about the first set of interviews. We had a sub-group of non-English speaking potential participants that we wanted to join the study, and I wanted to make absolutely sure that they understood what they were getting into.

Course Study Manual

Take a minute to explore the Resources section of this course in the top right corner of your screen. Here you'll find your social and behavioral Research Course Study Manual for this course, Informed Consent Communication. Be sure to print this before you continue.

Throughout this module you'll be able to pause the course and take notes specific to your institution. In the end, you'll have a roadmap to a successful social and behavioral research study.

Overview of Informed Consent Process

Let's start with the basics. What is informed consent? And why is it important?

Informed consent ensures that participants know exactly what is going to happen within a study, so they can make an educated decision about their participation.

It is an ongoing process and participants should be reminded of what each study visit entails. They may need to be re-consented if there are any changes to the study including a clinical protocol change or the identification of a new risk that could result in participant injury.

Regardless of how consent is acquired – whether it be a form, a video, an interactive computer module with comprehension checks, speak books or patient information sheets – all consent materials must be approved by your Institutional Review Board in advance of their use. This also includes materials translated into other languages.

The most important aspect to convey to all participants during the informed consent process is that a research study is just that…research. They should not be basing their participation on the expectation that they will be treated for a condition during the study.

Purpose of a Document

Again, the purpose of the informed consent document is to make sure study participants fully understand what they are signing up for. They may falsely believe that the study will provide a cure by participating. They could also feel pressured by others to participate, such as their doctor, family, or friends.

It is imperative that you review the entire informed consent document with participants and ensure that they understand exactly what you are telling them before proceeding with any aspect of the study.

In the next few minutes, we'll guide you through some best practices for this process and how to check participant comprehension.

Begin with your I.R.B. Template

So where do you start? Begin with a consent form template provided by your I.R.B. Typically, a principal investigator or research assistant will complete this document and customize each section to fit the study at hand.

Keep in mind that many terms may not be familiar to participants, so keep language simple. A good rule of thumb is to write using a sixth to eighth grade reading level. Lay-language resources are readily available on the internet and in the Resources section of this module.

Take a moment to find your I.R.B.'s version of an informed consent template. Write down any questions or comments you have about the document in your course study manual. You can contact your I.R.B. later to find the answers. When you're ready, click Next.

Elements of Informed Consent

You may be wondering, what are the critical elements in an informed consent document? Let's explore each one in more detail. Many, if not all, of these elements will be required by your I.R.B. Click each section to learn a bit more. When you're ready, click Next to move ahead.

Introduction

The Introduction should highlight the voluntary nature of the research, as well as what the participant can expect from being involved in the study. As you review this section with a potential participant, reiterate the importance of fully understanding this document, and encourage participants to ask questions.

The Introduction can also include the study's title, the sponsoring company or agency, and the names and credentials of the researchers involved.

Purpose

The purpose statement should describe the scientific reason behind the study's goals, but should be concise and easy for a layperson to understand. This section should be no more than one or two paragraphs.

Qualifications to Participate

This consent document element should list important eligibility and exclusion criteria, where applicable.

Design and Duration of Study

Here the participant should be given a complete and detailed picture of what will happen throughout the study. Study events are typically written in chronological order, and include details of expectations, procedures, assessments, and time frames. It is often a good idea to use

a range when providing numerical descriptions. This can help to minimize amendments to the I.R.B. protocol. For example, instead of noting that a follow-up visit will occur in one week, note a 7 to 10-day time period instead.

You can explain if there is a probability for random assignment in this section, as well. Be sure to also note how participant data will be collected, stored, and eventually destroyed.

Voluntary Participation

Emphasize that the participant is free to leave the study at any time, with no penalty. Include the procedure for withdrawal within the informed consent document, so participants know what to do if they would like to stop participating. Make sure to explain what will happen to their data if they withdraw early.

Alternative Treatments

Address other alternative treatments or options the participant may have if they decide not to take part in the study.

Possible Risks and Discomforts

Be sure to detail any known or expected risks or discomforts the participant may face as part of the study, as well as the likelihood of its occurrence. Also, be sure to explain how the study team will attempt to minimize these risks.

Benefits

Explain any benefits the participant may gain as a result of the study. It is important to note that any monetary or other compensation a participant might receive for participating in a study is NOT considered a benefit.

Compensation

Inform the participant of any compensation they will receive for participating in the study. Also, explain who will be responsible for paying for the costs incurred throughout the study. Specifically, note anything for which the participant or their insurer will be financially responsible.

Policy Regarding Research Related Injuries

Describe the process for participants to report illness, injury, or other problems due to study participation. The informed consent form should not waive or appear to waive any legal rights, or release or appear to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

Confidentiality

Explain to the participant who might see their information, and why they might need to see it. It will also be important to describe how the participant's confidentiality and privacy will be protected throughout the study.

Contact Information

List contact information, such as a mailing address, a phone number, and an email for the principal investigator and the study coordinator. Contact information for your I.R.B. should be included as well. Participants should be encouraged to contact the study team if they have any questions.

First Visit Preparation

Now that his informed consent document has been approved, it's time for Ken to begin preparing for his first participant visit. Let's look at some of the best practices he included in his checklist.

Depending on the study, a research assistant, coordinator, or even the P.I. may be conducting the informed consent interview and must be able to explain every element. This ensures that the participant fully understands the document before agreeing to participate.

Whenever possible, send a copy of the informed consent document to the potential participant ahead of time and ask him or her to write down any questions they have after reviewing it. Again, it is critical to remember that just because someone has read the document, it does not mean they understand it fully! You will still have to walk them through the document in person.

It might be helpful to have study team members practice the consent process with co-workers. Give feedback to each other to help anticipate questions and issues. You can also take time beforehand to prepare answers for participants regarding all aspects of the study.

The ideal physical room for obtaining consent is private and quiet. If you cannot secure a closed, private room, you could use a corner of a larger room or even your workspace if it is set apart from others. The risk to the participant is real if privacy is not ensured during consent, so take every precaution possible.

First Visit Conversation

The first visit with potential participants sets the stage for the entire study, so there are several best practices you will want to keep in mind. Consider using a checklist to make sure you've covered everything you need to. Let's see some of the steps Ken took to make his first informed consent interviews successful.

> Ken: "Good morning, Rita. How are you doing today?"
>
> Rita: "I'm doing all right."
>
> Ken: "That's good to hear! We'll be in this room for a little more privacy."
>
> Rita: "I've already read the document you sent in the mail last week, and I know I want to participate in this study. Do we really need to go over it now? I don't have any questions."
>
> Ken: "I'm so glad that you had a chance to read through the informed consent document, but I do have to review everything with you just to make sure that we're both on the same page and that you know what this study involves."
>
> Rita: "Ok, I guess we can do that."

Review the Informed Consent Document

First, review every section of the form with the participant. Even if someone has already read, signed, and dated the form, you should not take a shortcut or race through it. Be sure to encourage the participant to ask questions along the way.

Remember, it's possible that a participant has joined the study hoping for a cure to a condition, or to gain some other benefit. Once again, it is imperative to convey that the goal of the study is to learn, not to treat.

Be Conversational

> Ken: "As we walk through this document together, please don't hesitate to stop me if you have any questions. I shouldn't be the only one talking through this process."
>
> Rita: "Well… I do have one question. What happens if I don't want to participate in this study anymore?"

Ken: “That’s a great question. While we’d love for you to complete the study, your participation is entirely voluntary and you can stop anytime you’d like. We just ask that you let us know as soon as possible.”

Make Participants Feel Comfortable

You can be conversational in your recitation of the informed consent document. While all the elements must be discussed, the details can be fleshed out in a conversational manner. Show open and inviting body language, and always maintain eye contact to make the participant feel comfortable enough to ask a question. If you ask a question of the participant, try to use open-ended questions to encourage an open dialogue.

Keep in mind that sometimes it may be difficult to assess how much the study participant understands. Other issues like mild cognitive impairment and hearing or vision disabilities can also affect comprehension. Remember to keep your written and oral language between a 6th and 8th grade reading level. This will keep concepts simple and clear.

No matter what, do not pressure the participant. While you are asking for their help in the study, be careful not to push them into participation. Respect any potential reservations and talk through any questions participants might have. You must never coerce anyone into signing a consent form!

Participant Comprehension

Ken: “So, we just reviewed the details of what’s going to happen in this study. Can you tell me in your own words what the purpose is?”

Rita: “Sure. This study is going to be looking at my diet and how it affects my overall mood.”

Ken: “That’s exactly right. Now, can you tell me what you’ll be asked to do over the next few weeks?”

Rita: “I’ll be keeping a food journal and taking some surveys so you can see what I’m eating and how I’m feeling. Oh, and there are going to be some surveys that I need to complete when I come in for my check-in visits, too.”

Ken: “Excellent! Do you have any other questions that you’d like to ask me?”

Check for Participant's Understanding

Remember, just because you've walked through the consent document word for word, a potential participant may still not fully understand everything. Ask them questions surrounding different elements of the form, or have them explain the study in their own words. If you still feel they don't understand, you may have to repeat certain sections in a different way. Be patient, and allow ample time for questions. There is no wrong or silly question when it comes to comprehension! Sometimes additional educational materials are included as part of the I.R.B.-approved informed consent materials. Complex studies may also use comprehension checks, in the form of short quizzes.

Confidentiality

> Ken: "A lot of participants wonder about how our study team will be storing and protecting the data we collect. For this study, we'll identify participants using ID numbers, instead of names. Nothing you fill out will have identifying information, like your name, on it. We'll keep paper files in a locked cabinet in a locked office, and keep electronic files on a secure server that's password protected, and only accessible by our study team. We also won't share any of your information with anyone who is not on our research team. We take your confidentiality very seriously."

Maintain Confidentiality

During the consent process, it may become necessary to ask someone, such as a family member or friend, to step out of the room. The simplest way could be to say "I understand you want to be involved, but this involves a private conversation between Rita and myself." Of course, if the potential participant specifically asks for that person to stay, they should be allowed to do so.

You may not able to remove all influences, but ultimately the choice about participation needs to be made by the participant and you must do what you can to ensure that the final decision to participate is their own.

Many participants have concerns about confidentiality, and different studies require different types of information to be collected from participants. Even though it is a required part of the informed consent document, explaining privacy and confidentiality to the participant in a way they understand can help put them at ease about their participation.

Signing the Informed Consent Document

> Ken: “Rita, I really appreciate your time today. I know we’ve been here for a while and there’s just one last step. But before I have you sign our consent form, do you have any other questions?”
>
> Rita: “Yeah… who do I get in touch with if I have more questions during the study?”
>
> Ken: “Great question. Here at the bottom of the form is my contact information and the contact information for the Principal Investigator for this study. Please don’t hesitate to call us at any time! The number for the Institutional Review Board, who regulates our research, is also listed on the form. You can contact them if you want to talk to someone outside the study team about this research.”
>
> *Hands Rita the form*
>
> Ken: “This is our most current informed consent document and what I need from you is your signature and today’s date. I will also sign and date the form.”
>
> *Rita signs form*
>
> Ken: “Here’s your copy of the signed informed consent document. We’re looking forward to having you participate in our study.”

Obtain Signature

Be sure to allow ample time for the initial meeting, as the consent process can take up to 30 minutes or more, depending on how complex the study is and the length of the informed consent document. Before proceeding, double check that the most current informed consent document is being used. Once you are sure of the participant’s comprehension of the material, he or she must sign and date the informed consent form, then be given a copy. Team members must NEVER sign or date documents for the participant.

It is also a best practice to document the informed consent process in a study chart, including where the consent process occurred, who was present, participant questions and the given answers, and a confirmation that the participant was given a copy of the signed informed consent document. The original signed and dated form should be retained in the study record.

Subsequent Visits

Now the real work begins.

Before each visit, you should remind participants what they will be doing, answer any questions that they have, and confirm that they want to continue participating in the study.

Depending on the study and your I.R.B.'s policies, you may need to formally re-consent the participant at each visit. Your I.R.B. may also deem that re-consent is necessary if there have been any changes to the study. In this instance, you should make certain the participant understands the change, the reasoning, and what it means for him or her. Lastly, even if nothing in the consent form has changed, there are some studies that can last for years. It may be necessary to remind the participant of the consent elements with each visit.

Other Points to Consider

There are a few more important considerations to remember as you prepare your informed consent process. Click on each topic to hear a bit more.

Vulnerable Populations

There are special regulations for vulnerable populations, such as children, teenagers, cognitively impaired individuals, prisoners, and pregnant women. These regulations provide additional protections for these individuals, and may affect the consent process and document. Take a moment to review your I.R.B.'s guidance for vulnerable populations and make a note in your course study manual.

Consent vs. Assent

What's the difference between consent and assent? Consent forms are legal documents that can only be signed by adults 18 years of age and older. Assent forms give minors the opportunity to convey their own independent decision about participation in a study. Different assent forms may be required for a single study, depending on the ages of the children enrolled. Consult your I.R.B.'s Standard Operating Policies and Procedures for more details about assent, informed consent, and parental permission forms.

Coercion and Compensation

Are the participants making the decision to participate in the study independently? The risk of coercion from family members, friends, faculty advisors, professors and healthcare providers is real. A participant might also feel pressured to participate if there is a financial incentive for doing so.

Any financial amount should be appropriate for the amount of inconvenience the participant will experience. Your I.R.B. can help guide you on this and will approve a compensation plan during the I.R.B. protocol review process.

Violations

It is important to have procedures in place to ensure that the most current draft of an informed consent document is used. To prevent using the wrong form, avoid making several photocopies of a blank consent form all at once. Your safest bet is to print the consent form immediately before the study visit, and check the date to make sure the most recent version is used.

Additionally, a participant MUST sign and date a consent form properly prior to beginning any study participation. While it may seem like common ethical sense, a study team member must NEVER sign or date a form for a participant.

Course Study Manual Check-In

By now you should have filled in the Informed Consent Communication section of your Course Study Manual. If you haven't, take some time to complete this job aid. And don't forget to check out the Resources section for additional information and links, as well. When you're ready, click Next to move to the final assessment for this module.

Lessons Learned

That study was such a great experience. We were able to walk each participant through the process, gain rapport with them, and answer questions were needed. I also learned a few tricks that I can try out next time to make the process even smoother. All in all, we had a great study group, with participants who wanted the best outcome, just like we did. And we worked hard to keep each participant safe, happy, and informed. I'm proud of our team.