

# DECODING INFORMED CONSENT



The informed consent process is **YOUR** chance to make sure you have all the information you need to decide whether to take part in a clinical trial.

This handout explains what kind of information you will find in the different parts or “sections” of an informed consent form. It’s important to remember that each consent form may look a little different, and the words that your study team uses may not be exactly the same as the words used here. If you have any questions, or see any information that is listed in this handout but is not included in your informed consent form, please reach out to your study team!

## PURPOSE

- The Purpose section of the consent form will tell you why the clinical trial or study is being conducted.
- The reasons for the clinical trial should be explained in plain language so that you can understand the purpose without the help of a doctor or scientist.
- You might see sentences like, “The purpose of this research is...” or “The reason we are doing this research is to...”.

## PROCEDURES AND PROTOCOL

- The “Procedures and Protocol” will describe the exact procedures that will be followed in the course of the clinical trial (such as if blood will be drawn at the study visit(s) or any other medical procedures).
- This section will tell you if the clinical trial involves randomization or blinding, or if one group is given a placebo.
- For studies that involve a “placebo” group, this means that there will be a group within the study that receives a medication that looks similar to the actual medication but has no active ingredients (for example, a sugar pill). A study may also include a “sham procedure”, which is an inactive procedure that is designed to mimic as closely as possible the active procedure being studied in a clinical trial.

It is important to remember that some clinical trials for SMA require that all participants be untreated at the start of the trial. If a study requires participants that have never been treated, the description may use a term like “treatment naïve” to mean someone that has never had treatment for SMA. However, many new trials for SMA allow for participants to use currently available FDA-approved treatments in addition to the new treatment or medication.

Please see the [Cure SMA Clinical Trials](#) page for more information.

Cure SMA | 800-866-1762 | [cureSMA.org](http://cureSMA.org)



Cure SMA is a national organization that advocates for individuals with spinal muscular atrophy, a progressive neurodegenerative disease that robs people of physical strength, taking away their ability to walk, swallow, and breathe.

## DURATION

- The consent form should also tell you how long the clinical trial is expected to take. You might see a sentence like, “The clinical trial takes place over \_\_ (number of days)/or \_\_ (number of months) in total”.
- If the duration of clinical trial is unclear, make sure to ask the study team how long you are expected to be in the clinical trial.

## INFORMATION ON THE STUDY MEDICATION

- In this section, the consent form will provide some information about the medication being tested (if this is an interventional study). This may include information about the manufacturer, any known experience with the medication, and any known side effects.
- If other medications are also being used in the clinical trial, the side effects of these medications will be listed as well.

## RISKS

- The consent form will also describe any risks or discomforts that the researchers think participants may experience. These risks or discomforts may be described as “reasonably foreseeable risks.” For example, if the researchers plan to draw up blood samples, they will tell you that you may experience discomfort from the procedure.
- Risks may also include side effects that were discovered during earlier stages of the clinical trial. The informed consent form will include information about how the study team will secure care for you, including who will provide it and who will pay for it, if you or your child experience side effects during the clinical trial.
- **It is important to remember that a central goal of a clinical trial is to find out which side effects are associated with the study medication. Therefore, you may experience side effects that were not listed on the informed consent form. The study sponsor regularly evaluates the progress of the study and any associated side effects related to the study medication. If there are significant changes to the risks associated with the study drug, you will be provided with an updated consent form that includes the changes to the risks associated with the study drug to review and sign (also known as “re-consenting”).**
- The study team will do their best to provide you with enough information so that you can make the decision that is right for you.

## BENEFITS

- The informed consent form will also list any benefits that you may receive over the course of the clinical trial. These may include additional interactions with your study doctor during the trial.
- You will also be reminded that your participation can help future generations of people living with SMA!

## REIMBURSEMENTS

- In addition to benefits, the informed consent form should also list any financial reimbursement opportunities or stipends that are available for you. Reimbursements and stipends are ways of paying you back for things like travel costs or lost wages that you might have while participating in the trial.
- Don’t be afraid to ask the study team any questions you may have—if there is financial assistance, you are entitled to it!

## ALTERNATIVES TO PARTICIPATING

- The informed consent form will also include a section such as “Alternatives to Participating”. In this section, the study team will describe what treatment options are currently available for people living with SMA. Not participating in the clinical trial will almost always be listed as an alternative.

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## CONFIDENTIALITY

- The informed consent form will tell you how the study team will keep your information safe and confidential. The form should tell you what information is being collected, how the information is being stored, and who has access to it, including if sponsors or regulatory organizations will have access to it.
- This section will also tell you if the clinical trial sponsors are planning on publishing the results of the study.

## WHO TO CONTACT

- The study team will provide you with information about who to contact if you have any further questions about your rights as a research patient, the clinical trial itself, and in the event of a research-related injury.

## RIGHT TO REFUSE OR WITHDRAW

- The informed consent document will always tell you that your participation in the clinical trial is entirely voluntary, which means that participation is your choice. The form will also state that you can change your mind and stop participating at any time during the trial for any reason without any consequences to your standard of care.
- You may see sentences like, “Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change.”

## COLLECTION OF BIOSPECIMENS

- “Biospecimens” may be collected during the clinical trial. A biospecimen is any material from the human body, such as blood, plasma, tissue, or urine.
- On the informed consent form, the study team will tell you whether or not the biospecimens they collect during the trial can be used for other research purposes without asking again for your informed consent.
- Biospecimens will never have your name or any other identifiable information attached to them if they are used for another research project.
- You may also see a sentence like, “At the end of the research, in 1 year [or other amount of time], any left-over blood samples will be destroyed.”