

Study Talking Points Example: Sinusitis Trial

These talking points were developed for recruiters in a Sinusitis Study at the Children's Hospital of Pittsburgh of UPMC. Such a script can help assure consistency and thoroughness of the information shared with and across families during the recruitment process.

Sinusitis Talking Points

Your child has a sinus infection, also called 'sinusitis,' and Children's Hospital of Pittsburgh has a research program for children with these kinds of infections. This research will help us learn about the best way to treat sinus infections. Sometimes doctors treat sinus infections with antibiotic medicine right away. Other times, doctors wait a few days to see if the child gets better without medicine. We want to learn which option is better for children.

We do know that most sinus infections get better on their own, even without antibiotics. We also know that antibiotics have side effects such as diarrhea, rashes other allergic reactions. Also, antibiotics can cause the germs in your child's body to become resistant: the weak germs are killed, but the strong ones survive. When this happens, then antibiotics do not work. This makes it harder for doctors to treat future infections. So giving an antibiotic immediately to every child with a sinus infection may do some harm.

That is why we are doing this study. We want to find out if it is better to treat a sinus infection with an antibiotic right away, or if it is better to wait a few days to see if symptoms improve on their own.

If you decide to participate in our study, your child would start today, taking an antibiotic or placebo. A placebo is something that looks, smells and tastes like the antibiotic medicine but does not have any antibiotic in it. A placebo is not a new drug. We are not testing any new drugs. Your child would have a 50/50 chance of getting either an antibiotic or a placebo. You will not know and we will not know which treatment your child receives. This is ok because we will be following your child closely and because we do not know which is the best option. And, if your child is not getting better after 3 days, we will be sure to give him/her antibiotics. Every child in the research study receives the same high quality of care and close follow-up.

Also, if you decide to enroll, we will ask you to take a few minutes each day to fill out a diary that will let us know how your child is feeling. If your child is getting better, there is no need to change treatment. If your child's symptoms are not improving, we will start antibiotic treatment.

Study Talking Points Example: Sinusitis Trial

If you decide to participate:

Today, we will provide you the study medication and show you how to fill out the study diary.

Today, we will also get a sample of mucus from your child's nose to see what bacteria (or germs) may be causing your child's problem.

After today, we will see your child for one more visit in 2 weeks. This second visit should take 15 minutes.

You should also know that

- We will watch your child's health very closely. If you have any questions or concerns at any time – day or night, you can call our study team. We are available 24 hours a day, 7 days a week for any questions or concerns you may have.
- There are no costs to you for being a part of the study. Any time you come for a scheduled visit, you will get free parking and we will pay you for any travel expenses to get here.
- Your doctor supports this research study and would love to have your child participate. This will help us understand the most effective way to treat sinusitis in children.

Does this make sense to you? Do you have any questions or concerns?

Shall we go ahead and schedule *** for enrollment?

- If NO: Do you have specific concerns I can help you understand or discuss?
- If NO: Thank you for taking the time to speak with me.
- If YES: proceed and set up follow-up study visit.