

Assent Activity Booklet User Guide

- ▶ This customizable assent resource is intended for use by school aged children to communicate brief information about a study in child-friendly terms. There is no specific age range for this resource. It can be used for any type of study that would obtain assent. The resource is available in two versions, a puzzles version and a drawing version. Either or both may be used in your study. Feedback from children involved in designing these resources was to offer a broad range of activities. We suggest completing both versions and allowing each child to decide which (or both) activity booklet to do.
- ▶ This is not a prescriptive template and can be used to provide information in a way that is suitable for the study and study population. For example, these booklets can reflect information about the overall study. For very complex clinical trials, a booklet could be prepared to explain the activities of a single study visit. Alternatively, Pages 4 and 5 could be left blank for children to complete themselves as they go through the assent conversation with the study team.
- ▶ Assent is not a regulated activity, with no requirements for the process under Health Canada Part C, Division 5 of the Food and Drug Regulations. Obtaining assent is a process to determine a child's wishes regarding their participation in a study. Per TCPS 2, children may verbally or physically provide their assent or dissent, and providing a printed name or signature is not a requirement. Both verbal and physical assent can be obtained using the information in this resource and the faces.
- ▶ Colouring pens and pencils will be required for children to engage with these activities. Some children prefer to colour the images to match the typical colour of the object in reality, or to copy the colours used in the activity booklet. We suggest ensuring that a wide palette of colours is available for children that includes the theme colours. Stickers may also be used, for example with the 'decorate the ambulance' activity.
- ▶ Feedback from families included the following recommendations:
 - ▶ Provide limited high-level information so as not to be overwhelming
 - ▶ Introduce the study team that they will interact with as part of the assent information. This is important to children, and we suggest this is done at Step 1. See example below.
 - ▶ Use child-friendly language and avoid a 'pain-first' language, instead describing study activities using positive framing without centering fear or harm. Try describing activities using the senses (e.g. hot, cold, pinch, squeeze), along with positive encouragement.
- ▶ Both versions are intended to be presented as a booklet (printed and folded in half). To print this, flip on the short edge using letter size paper.
- ▶ Programs such as Adobe or Canva can be used to edit the template.

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- ▶ For Adobe: Select 'Fill in form fields' and then 'Type text'
- ▶ For Canva select 'Create' and then 'Upload'. Upload the template and then 'add text box'. To prevent the template from shifting, click on it and select the padlock image to lock it in place. Note: the upload may be blurry however when downloaded as a pdf this is corrected.
- ▶ There are 7 places to add text; the title (page 1 & 4) and 5 text boxes. Text can be included in the white spaces, see example below. Here are some suggestions:
 - ▶ Use a simplified title, not the protocol title or acronym title
 - ▶ What is the research about? – Provide a very brief description of the study
 - ▶ Step 1 – introduce the study team and study (the 'who', 'what' and 'why')
 - ▶ Step 2 – describe the study activities (the 'where' 'when', and the 'how long')
 - ▶ Step 3 – describe the study activities (the 'what and the 'how')
 - ▶ Step 4 – provide reassurances/information about how to contact the study team

Colour and Spot 12 Differences

RESEARCH LAB EDITION



THANK YOU!

WELCOME TO THE STUDY

DIET STUDY FOR KIDS WITH CROHN'S

What is research?



Research is a way to experiment and test new ideas. It helps us better understand health and disease, improve treatments, and find new cures.

What is a research study?



A research study is a project where scientists ask kids like you to help them learn more about sickness and health. We hope these studies will help kids today and in the future.

✓ When you and your family take part in a study, you are helping us improve healthcare for kids.

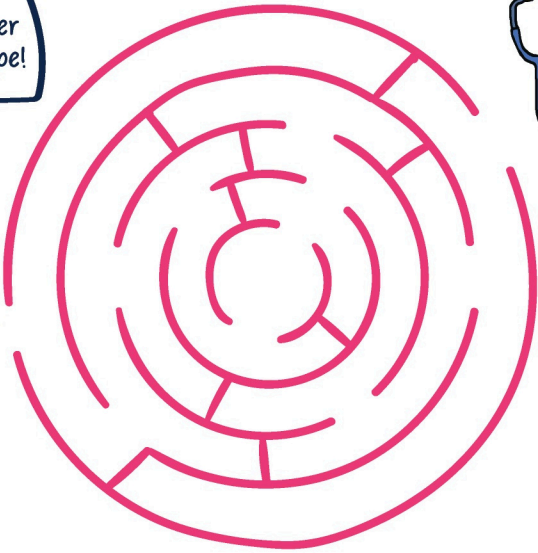
What is this research study about?

We want to know if a special diet can help kids like you feel better. Crohn's can mean that parts of your intestines can get swollen and sore. We want to find out if a special diet helps make you feel better sooner. Your trusted adult will be there to help you.

DECORATE YOUR NAME TAG



Help the researcher find the stethoscope!



Would You Rather?

PICK YOUR CARDS!

Shrink down and travel inside the human body.

OR

Have X-ray vision and see your bones.

Be able to hear heartbeats without a stethoscope.

OR

Check someone's temperature just by touching their hand.

Have a robot nurse helper.

OR

Have a talking microscope.

See food being digested in your stomach.

OR

See how your heart pumps blood through your body.

Circle The Words

AS MANY AS YOU WANT

What are your superpowers?

- I work well with others
- I ask good questions
- I like solving problems
- I am kind and helpful
- I think carefully
- I come up with ideas
- I stay focused

What helps you stay calm

- Listening to music
- Holding a comfort item
- Having an adult nearby
- Taking deep breaths
- Watching something
- Playing Games
- Asking questions

Draw your favorite thing to do!

Medical Kit

COLOUR AND NAME



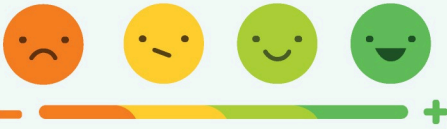
What do you think about this?



Being in a research study might be new for you. It is okay to have questions or feel unsure. We are here to help and answer your question. It's your choice to join the study. You, your trusted adult and the study team will decide together. If everyone says yes, you get to be in the study.

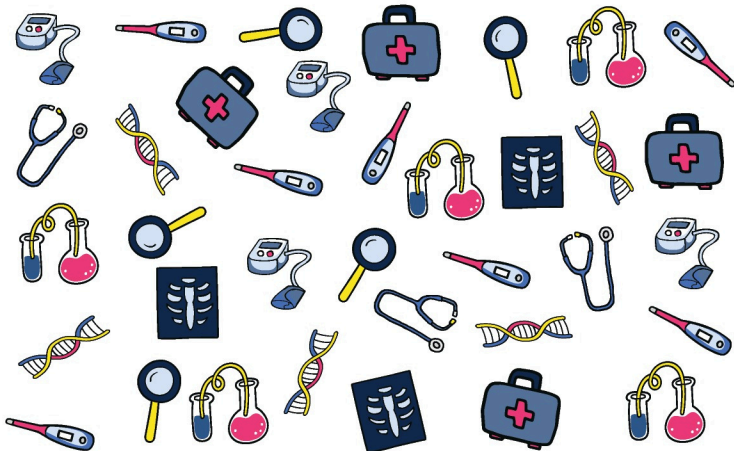
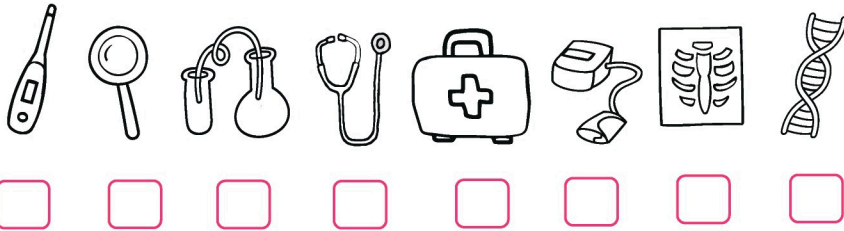
And remember, if you join and later change your mind, that is okay. You can stop at any time.

Circle the face that best shows how you feel!



I Spy: Research Edition

COLOUR, SEARCH AND COUNT



Why is research with kids important?

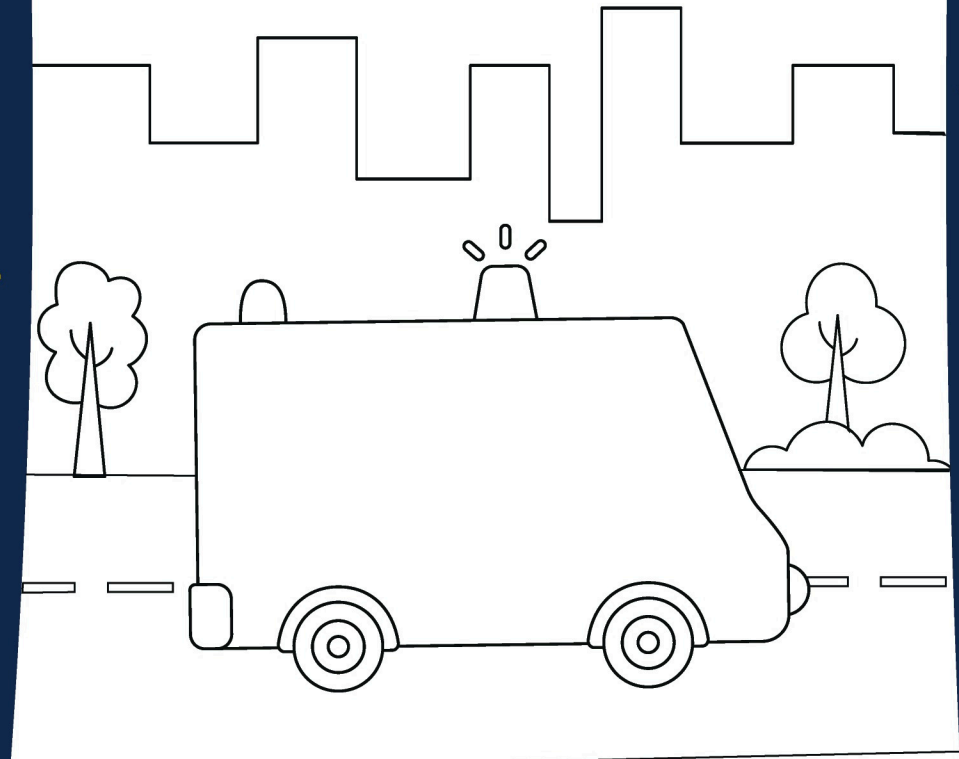


It is very important for children to be part of research studies to find treatments that are right for them. To learn new things about kids, researchers ask many questions and collect information so they can understand problems and come up with new ideas.

✓ The research team will not tell other people that you are in the study unless you and your trusted adult agree.

DECORATE THE AMBULANCE

DESIGN AND COLOUR



DIET STUDY FOR KIDS WITH CROHN'S

STEP 1

You will meet Dr. Elmo and the study team, we are the researchers doing this study. You will come to the hospital for your usual doctor's appointments, and we will see you at the same time. You will be in this study for about 4 months.

STEP 2

During this time, you will meet a nurse two times and they will do some simple tests and ask you a few questions. At home, you will fill out a short questionnaire each week about how you are feeling, your trusted adult can help you.

STEP 3

Other kids with Crohn's will be part of this study too. You will be split into two groups. Some kids will try a special diet, and some kids will try a different diet. Dr. Elmo and the team will choose which diet you are on.

STEP 4

Some parts of the study might make your Crohn's feel different than it usually does. If that happens you can tell us or your trusted adult. We are here to listen and try to make things better. You can tell your friends and family you are in the study if you like, no matter your choice, we will keep the information you share with us private.