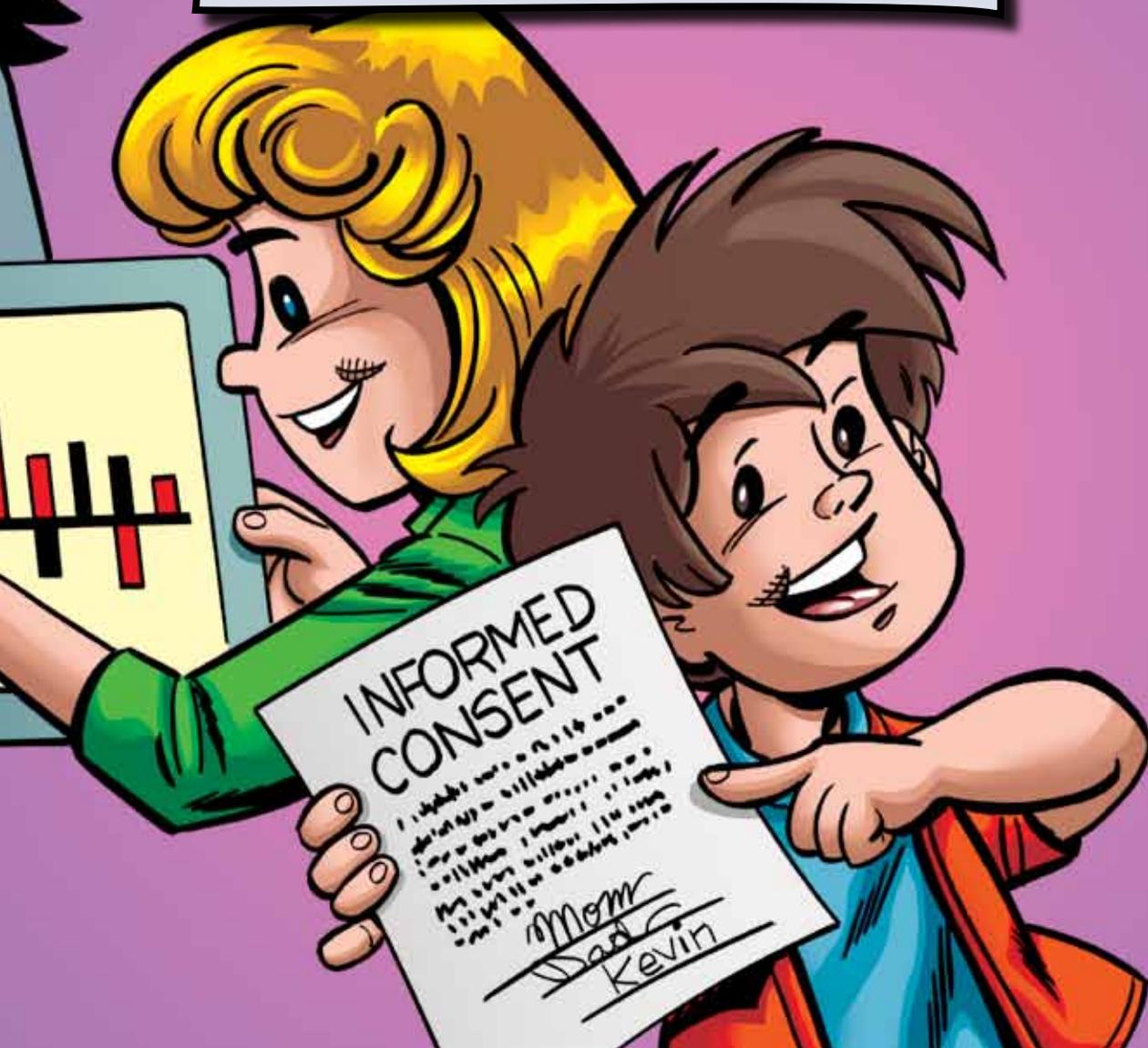


SOPHIE'S SCIENCE PROJECT

WHAT IS MEDICAL
RESEARCH?



Sophie's Science Project — A Note for Parents

IN ORDER TO CURE THE ILLNESSES THAT AFFECT CHILDREN, we must both understand the causes and develop new treatments. For this reason, doctors caring for children often ask families to participate in research studies. Medical research enables us to understand what genetic and environmental factors result in disease, and how illness affects a child's physical and mental health. There are many kinds of pediatric research, including questionnaires, studies that involve blood or fluid samples, and drug trials.

The ethical principles governing medical research are outlined in the Declaration of Helsinki and Belmont Report. In summary, the researcher must respect the child and parent's autonomy, and research "can never take precedence over the rights and interests of individual research subjects." In other words, parents and children who agree to participate in research do so of their own free will, and can change their minds at any time. In addition, it is the responsibility of the researcher to fully explain the nature of the study, as well as the risks and benefits, to the family. The informed consent document is a written explanation of the study, as well as the risks and benefits. When researchers and parents sign the informed consent, it means that an explanation of the study has taken place, and that the family understands the research and has willingly agreed to participate.

Children and teens are asked to give "assent" to a study. What "assent" means is that the child agrees to participate in the study. In many cases they are asked to also sign the parent's consent document or sign a special "assent form" that is specifically developed for their level of understanding. While the parental signature is the legal signature, the child's signature is additional evidence that they have been included in the consent process and are willing participants in the research.

We created *Sophie's Science Project* to educate children about medical research and the informed consent process. Children and teens who read this book will gain a better understanding of how doctors and scientists work together, what we do with the information we collect, and what it truly means to give "informed consent." We were lucky to enlist the superb writer and artist team of Hilarie and Joe Staton, who have developed other educational comic books for Boston Children's Hospital. We are also fortunate to have colleagues from Children's Hospital of Philadelphia and Cincinnati Children's Hospital, parents and other experts as advisors. As with our other educational comics, we hope both parents and children find *Sophie's Science Project* both fun and informative.

Athos Bousvaros MD, MPH
Susan Kornetsky, MPH

Consultants:

Robert W. Frenck, JR, MD
Cincinnati Children's Hospital Medical Center
Susan Kornetsky, MPH
Boston Children's Hospital
Skip Nelson, MD
U.S. Food and Drug Administration
Lois Russell
Research Subject Advocate
Mark S. Schreiner, MD
The Children's Hospital of Philadelphia

Editor: Athos Bousvaros

Writer: Hilarie Staton

Artist: Joe Staton

Design & Production: Victoria Ettlinger

Letterer: Janice Chiang

Colorist: Matt Webb

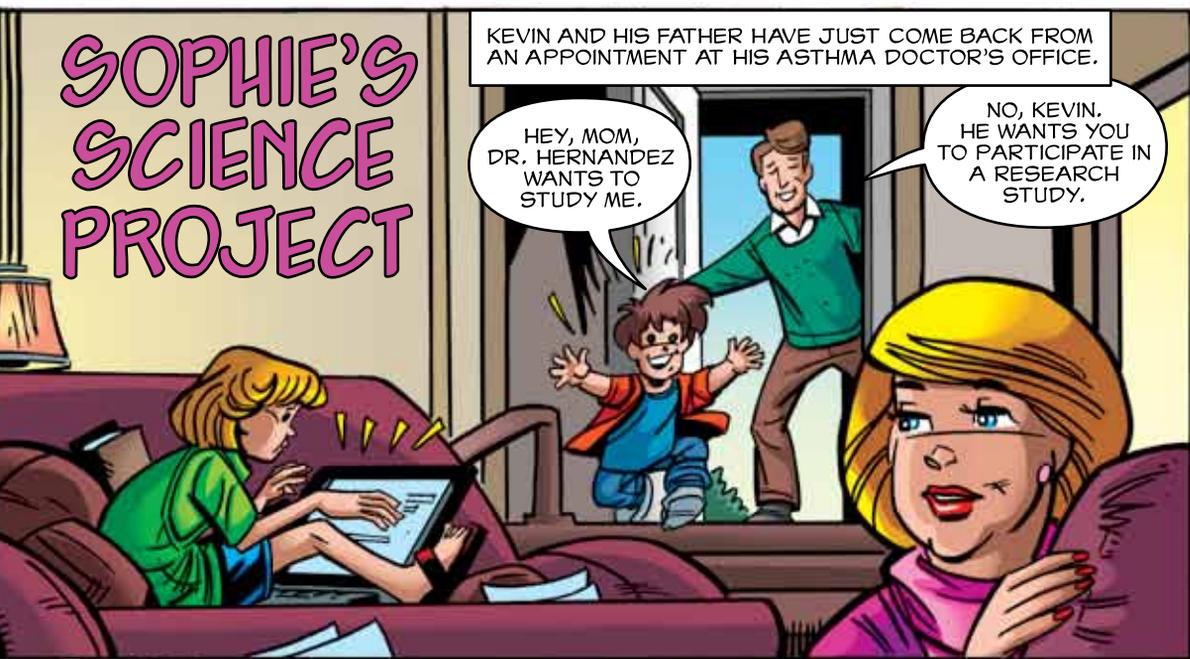
Proofreader: Maria Goudiss

SOPHIE'S SCIENCE PROJECT

KEVIN AND HIS FATHER HAVE JUST COME BACK FROM AN APPOINTMENT AT HIS ASTHMA DOCTOR'S OFFICE.

HEY, MOM, DR. HERNANDEZ WANTS TO STUDY ME.

NO, KEVIN. HE WANTS YOU TO PARTICIPATE IN A RESEARCH STUDY.

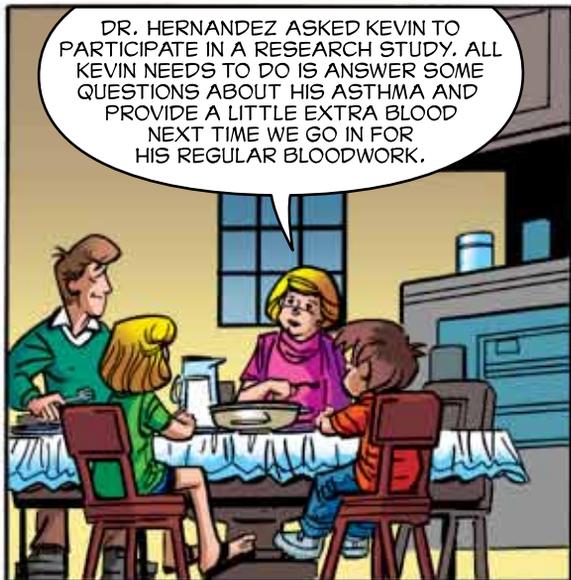


DO YOU THINK I SHOULD DO IT, MOM?

LET'S TALK ABOUT THIS AT DINNER, KEVIN.



DR. HERNANDEZ ASKED KEVIN TO PARTICIPATE IN A RESEARCH STUDY. ALL KEVIN NEEDS TO DO IS ANSWER SOME QUESTIONS ABOUT HIS ASTHMA AND PROVIDE A LITTLE EXTRA BLOOD NEXT TIME WE GO IN FOR HIS REGULAR BLOODWORK.



HOW MUCH EXTRA BLOOD DO THEY WANT?

YOU'VE GOT PLENTY!

DR. HERNANDEZ SAID ABOUT AN EXTRA TEASPOON.

THAT'S NOT MUCH, BUT IT'S UP TO YOU IF YOU WANT TO DO IT.

THEY WANT TO STUDY YOUR BLOOD TO LEARN WHAT CAUSES ASTHMA. THE DOCTOR WILL ASK SOME QUESTIONS TO FIND OUT HOW THE ASTHMA AFFECTS YOU. EVEN IF YOU SAY NO, DR. HERNANDEZ WILL STILL TAKE GOOD CARE OF YOU.





HMMM. I WONDER WHAT MEDICAL RESEARCHERS REALLY DO.

HEY, MOM. WHAT DO YOU THINK ABOUT USING MEDICAL RESEARCH AS THE TOPIC FOR MY SCIENCE REPORT?

DON'T SEE WHY NOT. YOUR AUNT BARBARA WAS IN A RESEARCH STUDY WHEN SHE WAS A TEENAGER. YOU CAN INTERVIEW HER. I BET DR. HERNANDEZ WOULD BE HAPPY TO TALK TO YOU, TOO.



SO WHAT IS THIS STUDY ABOUT, KEVIN?

HE WANTS ME TO HELP RESEARCHERS FIND THE CAUSE OF ASTHMA. I'LL BE FAMOUS!

KEVIN, I DON'T THINK YOU'RE GOING TO BECOME FAMOUS BY PARTICIPATING IN THIS STUDY. RIGHT, MOM? YOU AND A GAJILLION OTHER PEOPLE ARE PARTICIPATING IN THIS STUDY.



KEVIN, PEOPLE DON'T BECOME FAMOUS BY BEING IN STUDIES. DOCTORS KEEP PATIENT NAMES AND INFORMATION PRIVATE.

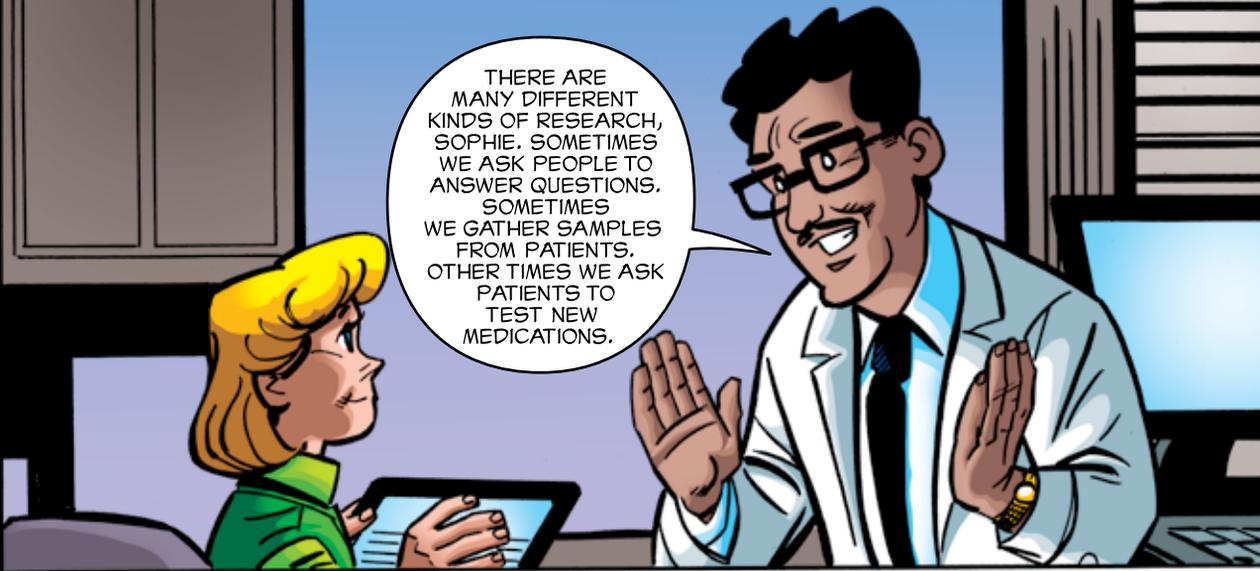
A WEEK LATER, SOPHIE GOES TO DR. HERNANDEZ'S OFFICE TO INTERVIEW HIM FOR HER SCIENCE PROJECT.



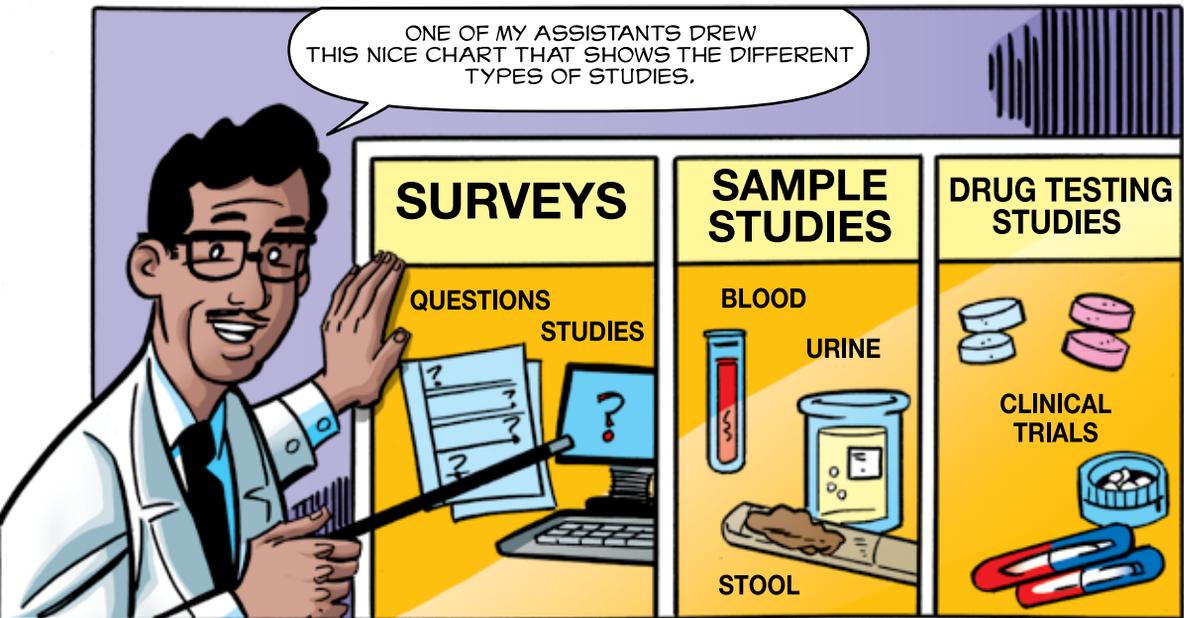
WHAT IS A MEDICAL RESEARCH STUDY, DR. H?

IT'S HOW WE LEARN, SOPHIE.

RESEARCH HELPS US IDENTIFY CAUSES OF ILLNESSES AND DEVELOP BETTER TREATMENTS.



THERE ARE MANY DIFFERENT KINDS OF RESEARCH, SOPHIE. SOMETIMES WE ASK PEOPLE TO ANSWER QUESTIONS. SOMETIMES WE GATHER SAMPLES FROM PATIENTS. OTHER TIMES WE ASK PATIENTS TO TEST NEW MEDICATIONS.



ONE OF MY ASSISTANTS DREW THIS NICE CHART THAT SHOWS THE DIFFERENT TYPES OF STUDIES.

SURVEYS

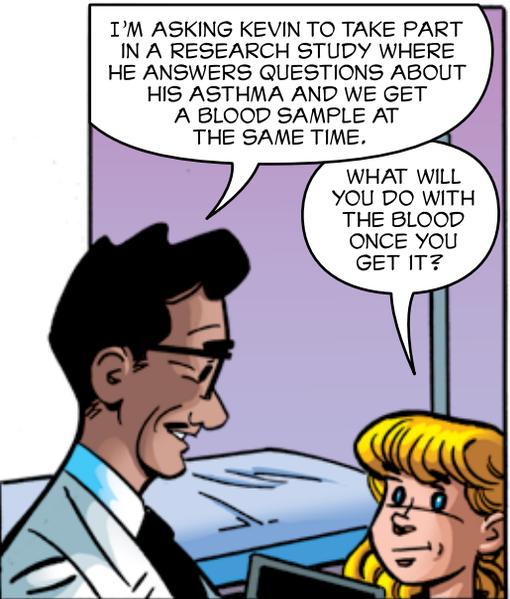
QUESTIONS STUDIES

SAMPLE STUDIES

BLOOD URINE STOOL

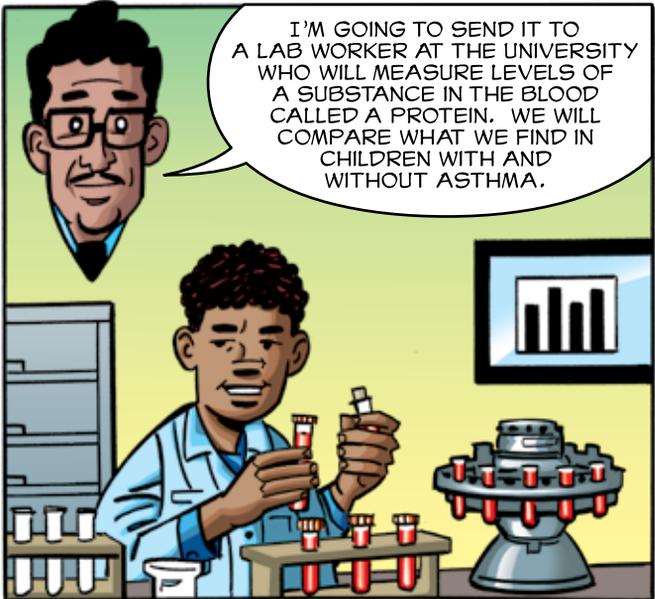
DRUG TESTING STUDIES

CLINICAL TRIALS



I'M ASKING KEVIN TO TAKE PART IN A RESEARCH STUDY WHERE HE ANSWERS QUESTIONS ABOUT HIS ASTHMA AND WE GET A BLOOD SAMPLE AT THE SAME TIME.

WHAT WILL YOU DO WITH THE BLOOD ONCE YOU GET IT?



I'M GOING TO SEND IT TO A LAB WORKER AT THE UNIVERSITY WHO WILL MEASURE LEVELS OF A SUBSTANCE IN THE BLOOD CALLED A PROTEIN. WE WILL COMPARE WHAT WE FIND IN CHILDREN WITH AND WITHOUT ASTHMA.



WHAT ABOUT THE QUESTIONS THAT KEVIN ANSWERS, DR. HERNANDEZ? HOW DOES THAT HELP YOU UNDERSTAND KEVIN'S ASTHMA?

HERE IS MY COLLEAGUE DR. LING TO BETTER EXPLAIN THAT, SOPHIE.

HI, SOPHIE!

I WORKED WITH DR. HERNANDEZ TO WRITE THE QUESTIONS THAT KEVIN WILL ANSWER. MOSTLY WE WANT TO KNOW HOW HIS ASTHMA AFFECTS HIS ABILITY TO GO TO SCHOOL AND EXERCISE, AND WHAT MEDICATIONS HE TAKES.

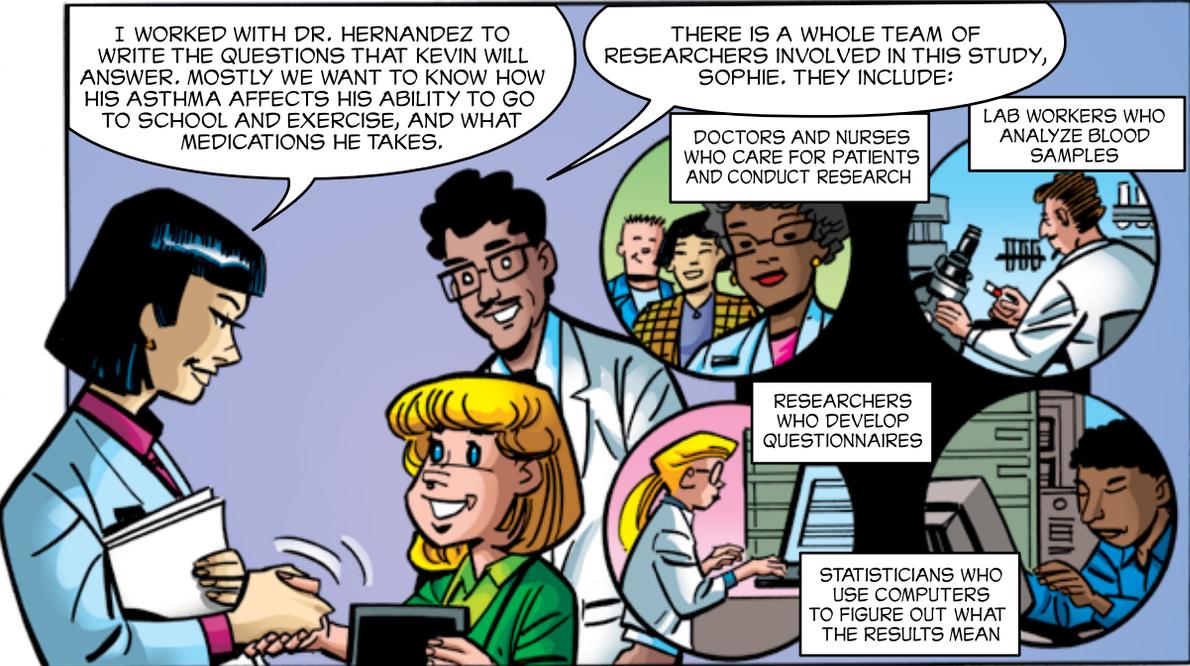
THERE IS A WHOLE TEAM OF RESEARCHERS INVOLVED IN THIS STUDY, SOPHIE. THEY INCLUDE:

DOCTORS AND NURSES WHO CARE FOR PATIENTS AND CONDUCT RESEARCH

LAB WORKERS WHO ANALYZE BLOOD SAMPLES

RESEARCHERS WHO DEVELOP QUESTIONNAIRES

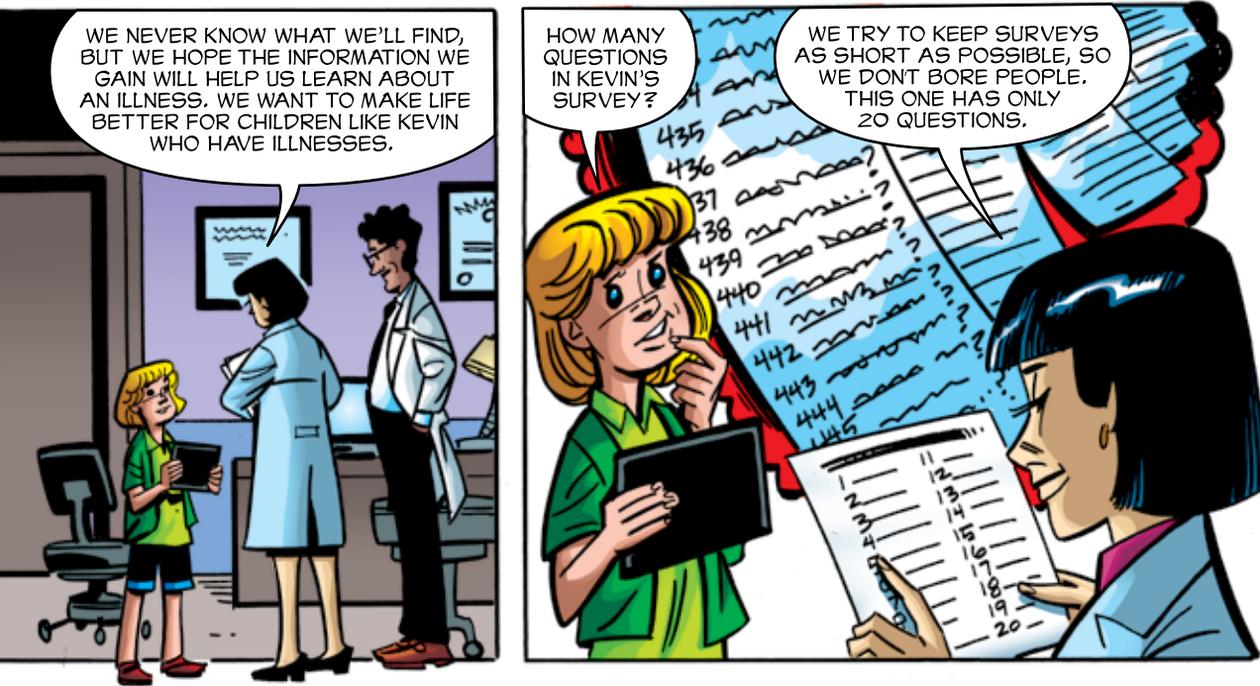
STATISTICIANS WHO USE COMPUTERS TO FIGURE OUT WHAT THE RESULTS MEAN



WE NEVER KNOW WHAT WE'LL FIND, BUT WE HOPE THE INFORMATION WE GAIN WILL HELP US LEARN ABOUT AN ILLNESS. WE WANT TO MAKE LIFE BETTER FOR CHILDREN LIKE KEVIN WHO HAVE ILLNESSES.

HOW MANY QUESTIONS IN KEVIN'S SURVEY?

WE TRY TO KEEP SURVEYS AS SHORT AS POSSIBLE, SO WE DON'T BORE PEOPLE. THIS ONE HAS ONLY 20 QUESTIONS.



AFTER VISITING THE DRUG COMPANY, SOPHIE AND HER MOTHER DROP IN ON SOPHIE'S AUNT.

I THOUGHT YOU MIGHT LIKE TO ASK AUNT BARBARA SOME QUESTIONS FOR YOUR PROJECT, SOPHIE.

I WAS PART OF A STUDY ABOUT TEENAGE DIETS.

ALL I HAD TO DO WAS ANSWER A BUNCH OF QUESTIONS ABOUT WHAT I WAS EATING.

"RAMEN NOODLES, BROCCOLI, POP TARTS..."

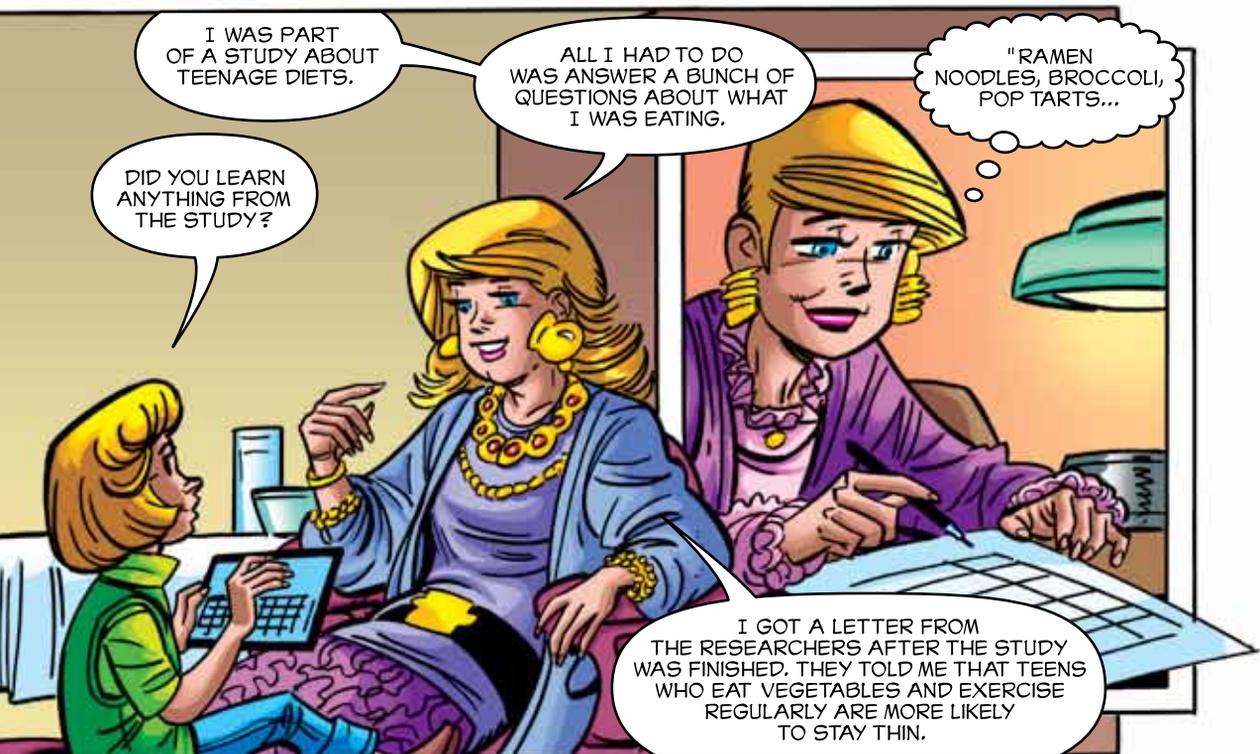
DID YOU LEARN ANYTHING FROM THE STUDY?

I GOT A LETTER FROM THE RESEARCHERS AFTER THE STUDY WAS FINISHED. THEY TOLD ME THAT TEENS WHO EAT VEGETABLES AND EXERCISE REGULARLY ARE MORE LIKELY TO STAY THIN.

I STILL TRY TO EAT HEALTHY.

MOM ALWAYS TRIES TO MAKE ME EAT HEALTHY FOODS.

DON'T FORGET EXERCISING AND DRINKING PLENTY OF WATER.



A FEW DAYS LATER IN DR. HERNANDEZ'S WAITING ROOM.

KEVIN'S REALLY DOING WELL. DR. H ASKED HIM TO PARTICIPATE IN A RESEARCH STUDY. NOW THAT WE ALL UNDERSTAND, WE'RE GOING TO SIGN AN INFORMED CONSENT DOCUMENT TODAY.

BRYCE IS DOING WELL, TOO, BUT WE'VE DECIDED NOT TO PARTICIPATE IN THE STUDY. WE NEED TO LEAVE RIGHT AWAY SO BRYCE CAN MAKE HIS SOCCER GAME.



DR. HERNANDEZ TOLD US THAT WHETHER OR NOT BRYCE IS IN THE STUDY, DR. H. WILL PROVIDE THE SAME MEDICAL CARE.

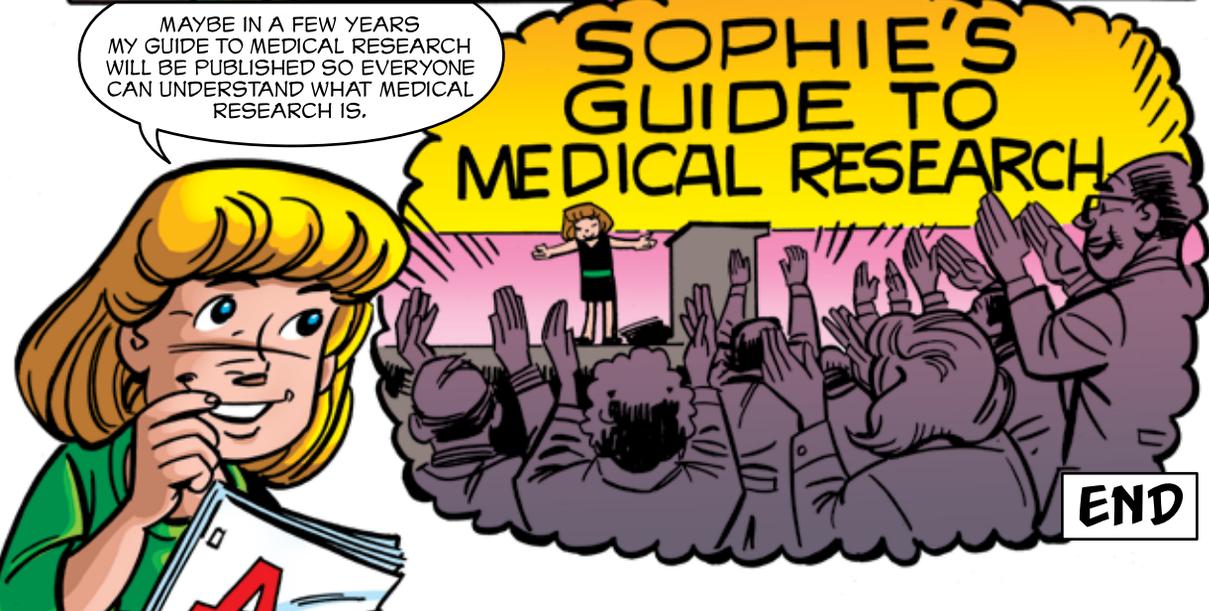
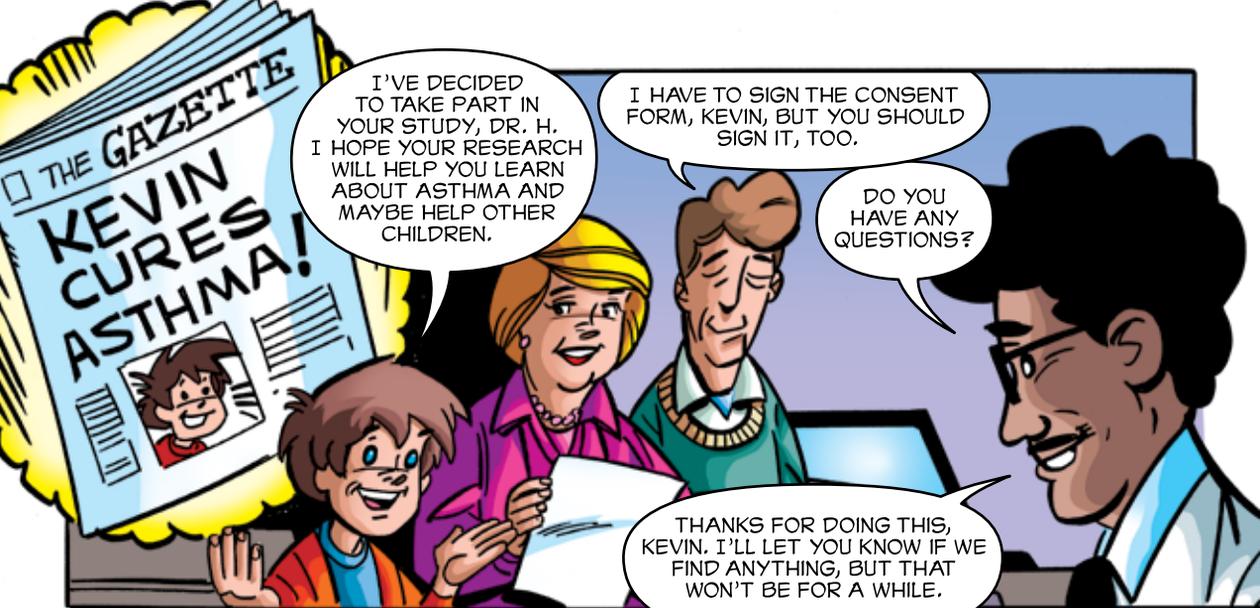
HAVE FUN AT THE SOCCER GAME. I'M GOING TO READ THE CONSENT FORM NOW.

INFORMED CONSENT

You are being asked to allow your child to participate in a research study about asthma. Participation in research is voluntary and you can say no or withdraw at any time. In this study, we want to learn more about the causes of asthma in order to develop better treatments. If you agree, your child will be asked to fill out a questionnaire and we will take an extra teaspoon of blood when your child is to have a blood test for another reason.

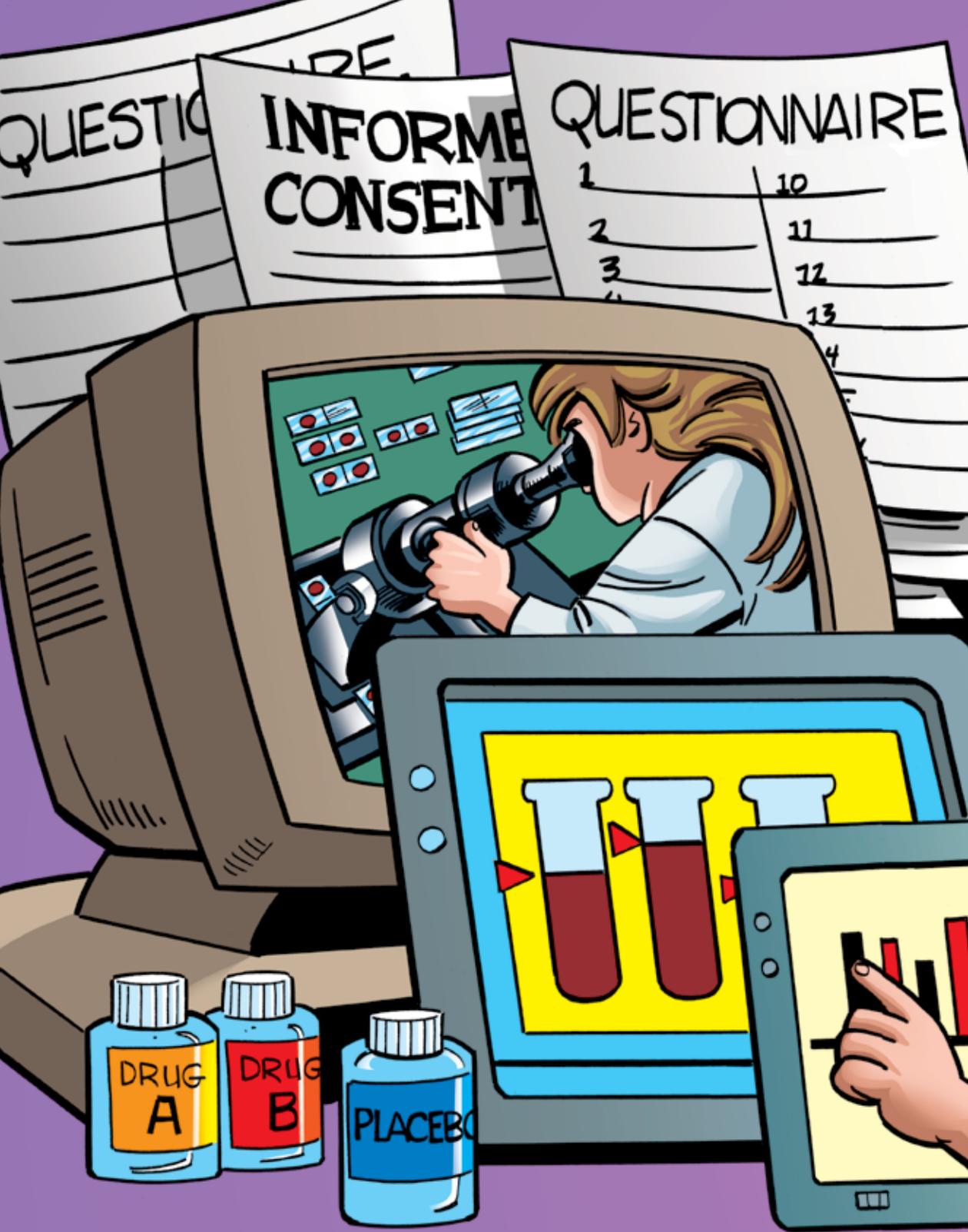
Signed: _____

Parent/Guardian for: _____



R*E*M*E*M*B*E*R

- * **Research is the way we learn** about the causes and treatment of illnesses.
- * There are **different types** of research. You may be asked questions, or have a blood sample taken, or you may be asked to try a new medication.
- * If **you decide** not to be part of the research study, you will still get medical care.
- * You can **ask questions** about the research at any time: before, during, or after you participate. Ask the researchers what they hope to learn from the study.
- * **Make sure you understand** what you will need to do for the research study. You might want to know how many times you need to come to the clinic as part of the study.
- * **Talk to your parents** about the research before you decide if you want to participate. Your opinion is important.
- * **You can stop** the research at any time. Just let your parents and the researcher know.



Boston Children's Hospital



Cincinnati Children's
Hospital Medical Center



The Children's Hospital of Philadelphia®