Quality of Care Evaluation Program: Research Study

This is a separate information sheet about the Quality of Care Evaluation Program (QCE) research study. You can still participate in the QCE program without participating in the QCE study. While the information you provide on these surveys will be used by hospital staff to help improve the quality of care at Seattle Children's or beyond, your participation in the QCE study would mean the survey answers you provide could be used more broadly for research. If you participate in the QCE study, the research team would take the answers you provide on these surveys and store them in a research database so they could be used in the future for research.

As noted in the program information sheet, these survey questions may be about your or your child's thoughts about:

➢ The quality of care you received
➢ Tests, treatments, or therapies
➢ The impact of some treatments or therapies on symptoms or quality of life

Since patients and parents/guardians can participate in the study, the word “you” and “your” in this form may refer to the patient and/or parent/guardian participant.

The surveys may also ask you some demographic information like your highest level of education or your access to resources in the home like the internet. If you choose to also share your data for research, we would also save a few pieces of information about you like your medical record number and the date of your visit, so researchers can link your survey responses to other information they need to answer their research question. You will not be asked to answer any additional questions.

This database would be available to researchers within and outside of Seattle Children's for the purpose of research. Researchers outside of Seattle Children's will only have access to your survey responses and not your medical record number. Before this information can be used, researchers will have to get review by an Institutional Review Board (IRB) for their study. Once they get review from the IRB, they will only be able to get the information they need to answer their specific research question from the research database.

You do not have to agree to add your data to the research database to answer the surveys or take part in the program.

How will the information I provide for research be used?
Identifiable information about you, such as medical record number, would be stored for 10 years after completing the survey. After 10 years, we would remove your identifiable information from the database. After that, we will only keep the survey responses, without any identifying information. This can be kept forever and may be used in future research.

If you join the research database, we will keep your information confidential as provided by law.

Your Privacy Rights
You have certain privacy rights regarding your Protected Health Information (PHI). Only with your permission may we create, use, or share your PHI for this study. The following describes
the types of PHI the study will create, use, or share, who may use it or share it, and the purposes for which it may be used or shared. PHI may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, or
- Information specific to you or your child like your name, address, birthday, ethnic origin, or identifying numbers like your social security number.

PHI may be created by, used by, or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Other people or organizations involved with your health care
- Review boards (such as Seattle Children’s Institutional Review Board), data and safety monitoring boards, and others responsible for overseeing the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries, or
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, or disability.

PHI may be created, used, or shared to:

- Study the results of this research,
- Check if this study was done correctly,
- Complete and publish the results of the study described in this form,
- Comply with non-research obligations (such as notifying others if we think you or someone else could be harmed), or
- Facilitate your health care.

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of your PHI may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, we will delete your information from the research database. However, information that we have already shared with other researchers prior to your cancellation may still be used.

Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We will not ask for your permission prior to this future research.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your
permission, no new information will be collected about you, but information that has already been collected may still be used and shared with others.

We will also put this form in your medical record. Medical records have different rules than research records. They are permanent and may be seen by others involved in your care, such as doctors, insurers, and others as required by law.

We will follow privacy laws when creating, using, or sharing your information, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you will not be used.

Your permission is documented by verbally or electronically agreeing to participate in the research database.

**What are the risks involved with participating in the research database?**
The risks of participation in this study include loss of confidentiality of your information if someone were to illegally access the research database. This risk is minimal as protected health information about you and your survey responses will be kept in a secure database that is only accessible to the QCE research team. Researchers who want to use this information for research purposes will need review by the IRB. We will send this information to them by creating a separate secure database of only the information they need to answer their research question and only the researchers listed in the IRB will have access to this separate database.

**What will researchers do with the findings? Will I be identified in the findings?**
The researchers may publish or present the research findings. You will not be identified in any findings that are published or presented.

**PERMISSION:** I agree to the sharing and use my information for purposes of this research study (i.e. storing this information in a research database).

Please let the staff know whether or not you give your permission or check the box on the first page of this electronic survey (if applicable) or on the first page of the mailed survey (if applicable).

**What will happen if I choose not to join the research database?**
Sharing your data with the QCE research database is completely voluntary. Your choice will not affect the care and treatment you receive at Seattle Children’s.

If you decide not to give your permission to take part in the research database, you do not need to do anything else. If we do not receive a written, verbal or electronic agreement, we will assume you do not want your information stored in the research database.

**What if I change my mind?**
If you are no longer a patient at Seattle Children’s or change your mind about having your information stored in this database, you can have it removed at any time. Please let us know in writing and we will remove your and your child’s information from the database. Write to the
Principal Investigator (PI)/Researcher of the database: Arti Desai, MD, MSPH (arti.desai@seattlechildrens.org).

Thank you for your consideration,

Arti Desai, MD, MSPH
Assistant Professor of Pediatrics
Center for Child Health, Behavior, and Development, Seattle Children's Research Institute
2001 Eighth Avenue, PO Box 5371, M/S CW8-6
Seattle, WA 98121

Outcomes Assessment Program
Email: OAP@seattlechildrens.org

Phone: 1-206-884-2555

Staff Member Only:

Patient's Medical Record Number: _____________________________

Staff Attestation (for patients with limited English proficiency)

☐ I have reviewed this information sheet with the family in their preferred language with a professional interpreter.

__________________________________________________________  _________________________________________
Staff Member Name                                                Staff Member Signature

Child Assent (if applicable for children 13-17 years)

☐ I discussed this study with the child participant using the assent script and the child participant agreed to participate in the QCE study.