




Fontan2 Links: [Parents/Patients](#) [Healthcare Providers](#) [Contact Info](#) [Brochures](#)



If you are the parent of a child who was enrolled in the Fontan Cross-Sectional (Fontan 1) Study and your child is less than 18 years of age, the word "you" refers to your child or adolescent who will be asked to participate in this study.



Fontan 2 Study Basics

You were enrolled in the Fontan Cross-Sectional Study or Fontan 1 Study that looked at how children and adolescents with single ventricle heart defects were doing after their *Fontan Surgery* .

 = glossary definition

Now we would like to learn how these children and young adults, who are now between the ages of 12 and 25 years, have done since the first study finished about six years ago. Therefore, we would like to collect more information about you.

The study will begin in November 2009 and all children who were enrolled in the original Fontan study will be invited to participate.

Who can be in the study?

You can be in the study if you were enrolled in the Fontan 1 study.

What do we have to do to be in the study?

The study will be explained to you in detail by one of the *study investigators* . Once your questions have been answered, you will be asked to sign an *informed consent form*  to enter the study.

This is what needs to be done in the study:

- **Medical Record Review:** We will contact you and look at your medical chart to obtain information about surgeries, tests or times that you were in the hospital. We will also ask if you are taking medicine or getting services like physical or speech therapy. You may be asked to sign a form allowing us to get information from other places where you have received or are receiving care.
- **Questionnaires:** Depending on your age, we will ask you or both you and one of your parents to complete questionnaires about yourself. Some of these questionnaires will be completed in a telephone interview. Others will be mailed to your home for you or one of your parents to fill out. The questionnaires will ask about physical, emotional, and social aspects of your health and about your quality of life. The questionnaires will also ask about your living situation, education, work outside the home, and other factors, such as health insurance coverage, that may affect your medical care.

This study does not involve any study-related visits.

Study personnel will be in contact with you during the time you are in the study. You are free to call the nurse or study coordinator at any time with any questions or concerns that you may have.

How long will we be in the study?

After you enroll and complete the questionnaires, we will continue to review your medical records and may also contact you once a year, by a brief telephone call or letter, for up to 10 years to see how you are doing. In addition, study personnel will keep you informed about other possible follow-up studies. However, you are not committed to entering any other studies.

What are the possible benefits to being in this study?

The questionnaires will provide information about how you act and function, which might not otherwise be known. If problems are found, early help can be suggested.


You may not benefit directly from being in this study, but the information we learn from this study may help improve the care of other children and young adults who have also been born with a heart defect.

What are the possible risks to being in this study?

You may find it inconvenient to complete the questionnaires or to talk with the study nurses by telephone. We will make sure that you will have plenty of time to fill out the questionnaires. You do not have to answer any questions that make you feel uneasy. Study nurses will be willing to answer questions or provide support as you complete the questionnaires.

What are the costs to me to be in the study?

There will be no extra costs to you when you join this study. You must pay for all other costs related to your normal medical care such as hospital stays, surgery, drugs, lab tests, and doctor's fees which are thought to be standard medical care for patients with your condition.

Fontan 2 for Healthcare Providers 

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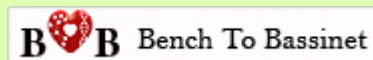
Department of Health and Human Services



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