CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
RESEARCH PARENTAL PERMISSION FORM

Sponsor / Study Title:	**Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD)/ "Prospective Observational Study of Asymptomatic cCMV Transmission to Infants for Virological Evaluation in New York State (PROACTIVE NYS)"**
Protocol Number:	**cCMV**
Principal Investigator: (Study Doctor)	**Andrew Handel, MD**
Telephone:	**(631) 444-7692** **(631) 689-8333 (24 Hours)**
Address:	**Stony Brook University Hospital** **101 Nicolls Road** **Department of Pediatrics** **Stony Brook, NY 11794-8111**

KEY INFORMATION

The information in this form is being used to seek your consent for a research study. Being in the study is voluntary. It is up to you. We are asking you to give permission for your child to participate in a registry, because s/he had a positive Newborn Screen or was diagnosed clinically with congenital cytomegalovirus (CMV) and we want to learn more about how these infants do over their first years of life. A registry is simply a reporting of how your child does over time. There are no medications associated with this registry. Any treatments or referrals will be part of standard of care for infants infected with CMV as recommended by your child's primary care physician team.

We would like your permission to obtain demographic and health information about your child from your child's medical records. This includes information collected by your child's doctor and other medical providers about things like what (if any) symptoms your child has, when their symptoms began, what diagnostic testing was done, and whether they received any treatment. We would also like to collect basic measurements like your child's height and weight over time. The information will be among items routinely collected by your child's doctor.

You are being asked to provide permission for your child to participate in this registry up until your child reaches at least 2 years of age. At that point, you may be asked to re-consent to continue your child's participation in the registry.

The most likely risk to you/your child is loss of confidentiality and privacy because personal health information is being exchanged. However, strict confidentiality procedures will minimize this risk.

We anticipate enrolling at least 500 infants in this research study.

See the **RISKS AND DISCOMFORTS** section of this form for a complete list of possible side effects

The most likely benefits to your child are: None, however this information may help doctors to better treat other newborns with congenital CMV.

If you decide not to allow your child to be in the research, your choices (if any) are: As this is not a treatment study, the alternative is to not participate.

You are being asked to allow your child to be a volunteer in a research study.

PAYMENT TO THE INSTITUTION

This project is funded, in part, by a grant or contract from the National Institutes of Health (NIH) to the Research Foundation of Stony Brook University, in support of the study doctors' work on this study.

PURPOSE

The purpose of this study is:

1. To better understand how children with congenital CMV are diagnosed, monitored, and treated.
2. Doctors can use the information to learn more about congenital CMV and how best to treat it.

PROCEDURES

If you decide to include your child in this study, his/her part will involve:

1. Your child's doctor will enter his/her health information into a secure online data collection system. The National Institutes of Health (NIH) is providing your

doctor's office with funding to support the time needed for their staff to enter the information from your child's health record into the registry.

2. Your child's doctor will enter the following information into the database about your child:
   - Your doctor's office location
   - Your child's date of birth, sex, race, and ethnicity
   - If the child's mother had a known CMV infection during pregnancy
   - How your child's CMV was diagnosed
   - Symptoms of the infection
   - Diagnostic testing results routinely ordered by your child's doctor (including bloodwork, radiology imaging, consults requested etc.)
   - Results of your child's hearing, vision, and developmental milestone testing
   - Any treatments given
3. Your child's doctor will ask you to complete surveys about your child's development and how CMV impact's the daily activities of your family and your child.

RISKS / DISCOMFORTS

The following risks/discomforts may occur as a result of your child being in this study:

- There is a small risk of loss of confidentiality and privacy because personal health information is being exchanged. However, strict confidentiality procedures will minimize this risk.

There may be risks which are currently unforeseeable.

BENEFITS

There is no direct benefit expected as a result of your child being in this study. Information learned from the study may help other people in the future.

YOUR PAYMENT FOR BEING IN THE STUDY

You will not be paid for allowing us to include your child's health information in the registry.

Your Payment for being in the study (if applicable)

__ I am a U.S. Citizen or Resident Alien. If paid $600 or more a year as a research subject, your social security number and amount paid will be reported to those in charge of taxes (IRS) by the Research Foundation and you may have to pay taxes on this money.

__ I am a Nonresident Alien. For tax purposes, all payments made to you must be done through the Research Foundation and are subject to a 30% tax withholding. All withholdings and payments will be reported to those in charge of taxes (IRS) by the Research Foundation.

YOUR CHILD'S PRIVACY IN THIS STUDY

To help make sure that all the information that is collected about your child is kept private, your child's name will not be used whenever possible. A code will be used instead. All of your child's study data will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your child's name will not be used.

While your child is in this study, the study doctor and study staff will collect and use data about your child's health from your child's medical record. Certain people and organizations will need to see, copy, and use your child's health data so that they can do their part in the study.

We want to make sure that this study is being done correctly and that your child's rights and welfare are being protected. For this reason, we will share the data we get from you and your child in this study with the study team, the sponsor of the study (and those who work for them), an institutional review board that reviews the study on an ongoing basis (Advarra IRB), Stony Brook University's Institutional Review Board, applicable Institutional officials, and certain federal offices, including the Office for Human Research Protections (OHRP), where applicable, the Food and Drug Administration (FDA), as well as your insurance company and your medical doctor (as applicable).

Your and your child's information will only be given out if the law requires it. For example, if you tell the study doctor that you are going to hurt yourself, hurt someone else, or if the safety of a child is at risk, the study doctor will have to tell the local authorities. In a lawsuit, a judge can make the study doctor or sponsor give him the information that has been collected about you or your child.

This study requires that we collect very personal information about your child. Therefore, we had the National Institutes of Health give us a Certificate of Confidentiality (COC). This piece of paper says that nobody can force the researchers to give out your child's information, even if a court of law asks for it. This will give your child more protection. The only time information about your child can be given out is:

- If your child is going to hurt him/herself.
- If your child is going to hurt someone else.
- If we believe the safety of a child is at risk.

If the data are required by other federal, state or local laws, such as for reporting of communicable diseases, you should know that the Certificate of Confidentiality does not apply to information about your child's participation in research, including a consent form that is placed in your child's medical record (though HIPAA protection does apply). This information may be disclosed to individuals requesting your child's medical record.

This Certificate doesn't mean you can't talk about this study. If you give written permission, your child's insurance company, your boss, or your medical doctor can be given the research information too.

The sponsor and those working for the sponsor may use the health data sent to them:

- For other research activities related to the study.

Your child's health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your child's rights and welfare are protected. Not all of these people are required by law to protect your child's health data. They might share it with others without your permission. For example, the sponsor paying for this study does not have to make the same promise under the law to protect your child's health data. However, sharing your child's health data will be guided by professional standards and the law.

Some of the health information from this study cannot be shared with you until the end of the study.

The use and sharing of your child's health information from this study will continue for an indefinite time.

However, you have the right to stop allowing the use or sharing of your child's health data. You can do this at any time by writing to the study doctor listed on page 1 of this form.

If you do this, the collecting of any new health data from your child will stop. Any data that is collected before you wrote your letter may continue to be used.

When you sign this form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your child's health data as described above.

If you do not allow the use and sharing of your child's health information, your child cannot take part in this study.

FUTURE RESEARCH STUDIES

Your private information collected during this study **will not be used or distributed for future research studies,** even if identifiers are removed.

COSTS

It will not cost you any money to have your child's information shared with the registry. Costs associated with your child's medical care will continue to be your responsibility.

ALTERNATIVES
Your child's alternative to being in this study is to simply not participate.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00074789.

Visit Stony Brook University's Community Outreach page, http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-in-research for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

SUBJECT RIGHTS

- Your child's participation in this study is voluntary. Your child does not have to be in this study if you don't want him or her to be.
- You have the right to change your mind and withdraw your child from the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about your child being in this study will be given to you.
- The information in this form reflects what is known about the research study at the time it is signed and dated. Any new information that may make you change your mind about your child being in this study will be given to you.
- You will get a signed copy of this consent form to keep.
- You do not lose any of your or your child's legal rights by signing this consent form.

STATEMENT OF CONSENT AND AUTHORIZATION

I have read this form and its contents were explained. I agree for my child to be in this research study. I also give permission to the study staff to use and share my child's health information for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a copy of this form for my records. I am not giving up any of my or my child's legal rights by signing and dating this form.

_____ ____/____/____

Signature of Research Subject's Parent or Legal Guardian Date

_____

Printed Name of Research Subject's Parent or Legal Guardian

STATEMENT OF PERSON EXPLAINING CONSENT AND AUTHORIZATION

I have carefully explained to the subject's parent or legal guardian the nature and purpose of the above study. There has been an opportunity for the subject's parent or legal guardian to ask questions about this research study and this form. I have been available to answer any questions that the subject's parent or legal guardian has about this study and this form.

_____ ____/____/____

Signature of Person Explaining Consent and Authorization Date

_____

Printed Name of Person Explaining Consent and Authorization