Approved by the Nemours IRB
Valid From: July 31, 2019
to January 2, 2020
[456569]

Nemours
Parental Permission for Participation in an Observational / Non-Interventional Research Study

Nemours PP Non-interventional Template March 2018

You have been asked to permit your child to be in a research study. If you are a parent or legally authorized representative of a child who may take part in this study, permission from you is required. This form explains the research, your child's rights as a research participant, and any responsibilities that you may have as a result of your child's participation. You should understand the research study before you agree to permit your child to be in it. ***You will receive a copy of this form. Read this permission form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.***

1. WHAT IS THE TITLE OF THE STUDY?

Rhizomelic Chondrodysplasia Punctata Registry at A.I. duPont Hospital for Children

2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

	Nemours - WIL
Principal Investigator	Michael B. Bober, MD, PhD AIDHC-Medical Genetics, 302-651-5916
Co-Investigator(s)	Angela Duker, Tim Niiler, Nga Hong Brereton, Nancy Braverman, Matthew Di Guglielmo, MD, PhD, Ricki Carroll, MD
Study Coordinator(s)	Cassondra Brown, MS AIDHC-Medical Genetics, 302-298-7930
Address	Nemours/Alfred I. duPont Hospital for Children 1600 Rockland Road Wilmington, DE 19803
Long Distance	1-800-SOS-KIDS (1-800-767-5437)

3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?

If you have questions about your child's rights as a research subject, what to do if your child is injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Chairperson, Nemours IRB 1 at 302-651-5970
Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

4. WHAT IS THE PURPOSE OF THE STUDY?

You are being invited to allow your child to participate in a data collection effort called a registry. The goal of this registry is to collect information on individuals with Rhizomelic Chondrodysplasia Punctata (also called RCDP) and other related conditions. The study team hopes to learn more about these diagnoses and improve the care of people with it by establishing this registry.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

RhizoKids International is the Sponsor of this study. RhizoKids International will pay Nemours for its costs in conducting this study.

6. WHO CAN BE IN THE STUDY?

Individuals with RCDP types 1, 2, and 3 and other closely related conditions as diagnosed by a physician are eligible for this registry.

7. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

Approximately 100 individuals with RCDP and other closely related conditions will be enrolled in the study.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

This study is limited to chart review. There will be no additional visits or time in clinic because of your child's participation in this registry. The study team believes participation will last for at least 5 years.

9. WHAT ARE THE RESEARCH PROCEDURES?

This study involves only the collection and storage of data extracted from the medical record. There are no special procedures, visits, or expectations of your child as a result of participation in this registry. Your child will not be asked to have any specific testing for the sole purposes of research. If you give permission, we may contact you to request additional information, ask about any new medical problems, or ask you to complete questionnaires about your child's health and daily activities.

Patient at AIDHC

If your child has had lab work or imaging studies performed at AIDHC these records may be reviewed to gain additional information about this condition. Records that may be reviewed as a part of this study include but may not be limited to ophthalmologic evaluations, x-rays of bones and other imaging, and results of blood and urine tests.

Patient outside of AIDHC

You may have heard about this study by viewing information on the RhizoKids International website (www.RhizoKids.org) or the Nemours Skeletal Dysplasia Program website (http://www.nemours.org/skeletaldysplasia). You downloaded the study information, medical records release, and informed consent forms from one of these sites. You reviewed the information and contacted the study team to have any questions or concerns answered to your satisfaction. Dr. Michael Bober or a team member was contacted at (302) 651-5916 or mbober@nemours.org to enroll in the study. You may make records and/or x-rays from other hospitals and doctor's offices available to the study team if you wish. Records that may be reviewed as a part of this study include but may not be limited to ophthalmologic evaluations, x-rays of bones and other imaging, and results of blood and urine tests.

The following will be mailed to the following person and address:

Michael B. Bober, MD, PhD
Alfred I duPont Hospital for Children
Medical Genetics
1600 Rockland Road
Wilmington, DE 19803

Items mailed:

- ❑ 1 copy of informed consent with original signature
- ❑ 1 copy of medical release form with original signature
- ❑ Medical records and medical images (x-ray and/or MRI)

By agreeing to be in the registry, you allow study team members to review your child's medical records and collect information about their condition.

10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?

The risks involved in this study are the same as the risks your child would ordinarily encounter in daily life or during a routine physical examination. This research is observational which means that there is no change to any treatment that your child may be receiving. The possible risks are described below.

The most common risk of participation in a registry is the chance that your child's private information (ex: status of health, treatments prescribed) may be used for purposes other than those described in this permission form. Loss of privacy may affect your child's insurability, employability or may result in labeling of a person with a chronic illness. The protection of your child's confidential information is described in Section 16 of this form.

11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

There is no direct benefit to you or your child from participating in this registry. Participation in this registry may help doctors to better understand the disease process and identify a standard of care for individuals with RCDP and related conditions.

12. IS BEING IN THE STUDY VOLUNTARY?

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your child's usual medical care if you decide not to permit your child to be in the study or decide to stop your child's participation in the study. No one will be angry with you or your child, or treat your child any differently than before your child was asked to be in the study.

You may ask the researcher to destroy your child's information or samples. Your request must be in writing. The researcher will tell you if this is possible. There may be legal reasons for keeping your child's information or samples.

13. WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There are no direct costs to families for participating in this registry. Costs related to your child's regular care will still be your or your child's insurance company's responsibility. Regarding obtainment of medical records, as the sponsor, RhizoKids International will ensure that all participants will have no cost associated with mailing information to Nemours. If needed, a pre-paid mailing envelope can be forwarded to all participants by a representative from Rhizokids International.

14. WILL MY CHILD BE PAID FOR BEING IN THIS STUDY?

Participants will not be paid for participating in this study. No arrangement exists that would allow participants to share in any profit generated from this study or future research.

15. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO PERMIT MY CHILD TO STAY IN THE STUDY?

Any new information that may change your mind about allowing your child to be in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while your child is taking part in this study, it will ask the study doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

16. WHAT INFORMATION ABOUT MY CHILD WILL BE USED OR DISCLOSED? (AUTHORIZATION TO USE AND / OR DISCLOSE PROTECTED HEALTH INFORMATION)

Identifiable health information about your child will be used by Nemours researchers and may be given to people outside of Nemours for this research. This is done to conduct the research study, to monitor the safety of research participants and for auditing. Federal law requires us to tell you about, and get your approval for research use and disclosure of health information that includes "identifiers" that can connect the health information to your child. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This Identifiable health information is called Protected Health Information (PHI).

Use of Health Information by Nemours Staff

The health information that will be used within Nemours includes all data collected for this study, as described in Section called "What Are the Research Procedures?"

Your child's identity will be protected as much as possible. Nemours protects you and your child's health information by storing records in files or computers that can only be used by authorized Nemours staff.

The people within Nemours that may use this health information include:

- The investigators listed on the first page of this permission form and their staff,
- The Nemours Institutional Review Board (IRB) (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and;
- Nemours internal audit staff.

Disclosure of Health Information to Others

Identifiable health information will be disclosed (given) to the following individuals or groups:

- Health information in your child's medical record shared with the study funder (sponsor) or their agent is limited to information directly related to this research study.
- Co-investigators as listed on the first page, some of whom are employed outside of the Nemours system.

The PHI that will be disclosed (given) to people or groups outside of Nemours for research purposes are listed in the table below:

Type of Identifiable Health Information:	Disclosed
History and Physical	☒
Results of Procedures	☒
X-Ray Reports	☒
Surgery Reports	☒
Genetics Studies	☒
Demographics (information about race, ethnicity, gender, age)	☒
Imaging studies (MRI, CT, xray, ultrasound)	☒
Biochemical studies	☒
Questionnaires	☒

Limits on Protection of Privacy and Confidentiality

Only health care organizations have to follow laws and rules about protecting the privacy of health information. If health information containing peoples' identities is given to other kinds of companies or organizations, they are not required by law to safeguard the privacy and confidentiality of that information.

Nemours expects these companies and organization to protect the privacy and confidentiality of research participants, but it is not possible for Nemours researchers to assure that this happens.

Government agencies that may look at records for this research study, including the above health information, include:

- The U.S. Food and Drug Administration
- The U.S. Department of Health and Human Services
- Other agencies of State and local government as required by law

The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

17. SIGNATURES:

I am making a decision whether or not to permit my child to participate in this study. I understand that my child may also have to agree to participate in the study before he/she will be allowed to be in this study. I have read this form, or have had it read to me in a language that I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can withdraw permission for my child's participation in this study and for the use and/or disclosure of my child's PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and/or disclosure of my child's PHI will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- Unless I withdraw permission, the use and/or disclosure of my child's PHI described in this form will not have an expiration date.
- My child's PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this permission form.
- If I refuse to sign this permission form, my child will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my child's protected health information.
- I have the right to revoke my permission for the use and disclosure of my child's health information at any time, which would end his/her participation in this study.
- I will receive a signed and dated copy of this form.

Parent / Legal Guardian Signature Section

My signature indicates that:

- As his or her parent(s) or legally authorized representative(s), I(we) give my(our) permission for the minor child named below to participate in the research study described in this Parental Permission Form.
- I(We) give the researchers and Nemours permission to use and / or disclose my(our) child's individually identifiable health information for this research study as described in this form.

Name of Participant (**Print**)	Participant Date of Birth
Name of Parent / Legally Authorized Representative (**Print)**	
Signature of Parent / Legally Authorized Representative	Date

(#1)

Check Relation to Participant: ☐Parent☐ Legally Authorized Representative
(Legally Authorized Representatives must have documented authority to give permission for a child's participation in a research study according to the laws of the State in which the treatment occurs.)

Second parent signature ☐ N/A
Do NOT check this box if the IRB determined that two (2) parent signatures are required as noted in the IRB final approval correspondence.

Name of Parent / Legally Authorized Representative (**Print)**

Signature of Parent / Legally Authorized Representative (#2)

Date

Check Relation to Participant: ☐ Parent ☐ Legally Authorized Representative
(Legally Authorized Representatives must have documented authority to give permission for participation in a research study according to the laws of the State in which the treatment occurs.)

Study Team Member Signature Section
I, the undersigned, certify that to the best of my knowledge the parent(s) / legally authorized representative(s) signing this permission had the study fully and carefully explained and that she / he (they) understand(s) the nature, risks and benefits of their child's participation in this research study.

I, the undersigned, certify that the participant completed no research procedures for this study prior to signing this permission.

Name of Person Obtaining Permission (**Print**)
(Investigator or Designee)

Signature of Person Obtaining Permission
(Investigator or Designee)

Date

A copy of the signed form was provided to Parent(s) / Legally Authorized Representative(s) ☐

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ADDENDUM FOR *OPTIONAL* FUTURE CONTACT

We may need to contact you in the future by phone, mail or email to request additional information, ask about any new medical problems, or ask you to complete questionnaires about your child's health and daily activities. Please indicate whether or not you would want to be re-contacted by checking the box below:

- ❑ Yes, I do wish to be re-contacted.
- ❑ No, I do NOT wish to be re-contacted.

If you permit researchers to contact you again, please give your current contact information in the space below. Please notify the study coordinator, Cassondra Brown, if your contact information changes.

Address_____

Phone _____, email _____