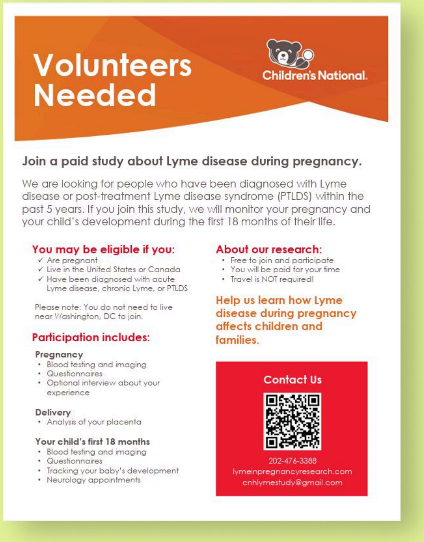
Lyme in Pregnancy Research Recruitment Toolkit

Last Updated June 2025

On behalf of the Lyme in Pregnancy research, thank you so much for partnering with us to advance our study, *Pregnancy and Early Neurodevelopmental Outcomes Following In Utero Lyme Disease Exposure*. We truly mean it when we say we couldn't do this work without you!

Below is information about each resource in the Recruitment Toolkit.

For additional information, questions, or suggestions about resources to add, please contact the study team at cnhlymestudy@gmail.com.



Volunteers Needed

Children's National.

Join a paid study about Lyme disease during pregnancy.

We are looking for people who have been diagnosed with Lyme disease or post-treatment Lyme disease syndrome (PTLDS) within the past 5 years. If you join this study, we will monitor your pregnancy and your child's development during the first 18 months of their life.

You may be eligible if you:
- ✓ Are pregnant
- ✓ Live in the United States or Canada
- ✓ Have been diagnosed with acute Lyme disease, chronic Lyme, or PTLDS

Please note: You do not need to live near Washington, DC to join.

Participation includes:

Pregnancy
- Blood testing and imaging
- Questionnaires
- Optional interview about your experience

Delivery
- Analysis of your placenta

Your child's first 18 months
- Blood testing and imaging
- Questionnaires
- Tracking your baby's development
- Neurology appointments

About our research:
- Free to join and participate
- You will be paid for your time
- Travel is NOT required!

Help us learn how Lyme disease during pregnancy affects children and families.

Contact Us

202-476-3388
lymeinpregnancyresearch.com
cnhlymestudy@gmail.com

Study Flyer

Please share this flyer online or print and post it in your clinic, office, or community! If you are unable to print and would like to receive hard copies of the flyer in the mail, please email mewilliams@childrensnational.org.

"I was just diagnosed with Lyme disease. Will that affect my baby?"

Join our study or learn more at lymeinpregnancyresearch.com

Children's National.

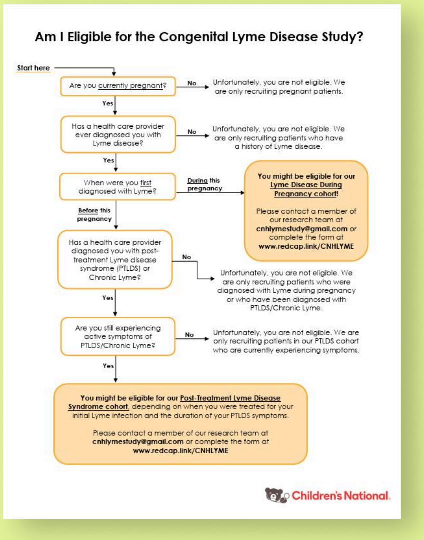
Please note: You do not need to live near Washington, DC to join. The study can be done remotely.

Your child's first 18 months
Blood testing and imaging
Questionnaires
Developmental assessment
Neurology appointments

- Visit our website at lymeinpregnancyresearch.com
- Scan the QR code above

Study Postcard

This printable double sided postcard gives details about our study. If you are unable to print and would like to receive hard copies of the postcard in the mail, please email mewilliams@childrensnational.org.



Am I Eligible for the Congenital Lyme Disease Study?

Start here

Are you currently pregnant? — No → Unfortunately, you are not eligible. We are only recruiting pregnant patients.

Yes ↓

Has a health care provider ever diagnosed you with Lyme disease? — No → Unfortunately, you are not eligible. We are only recruiting patients who have a history of Lyme disease.

Yes ↓

When were you first diagnosed with Lyme? — During this pregnancy → You might be eligible for our Lyme Disease During Pregnancy cohort! Please contact a member of our research team at **cnhlymestudy@gmail.com** or complete the form at **www.redcap.link/CNHLYME**

Before this pregnancy ↓

Has a health care provider diagnosed you with post-treatment Lyme disease syndrome (PTLDS) or Chronic Lyme? — No → Unfortunately, you are not eligible. We are only recruiting patients who were diagnosed with Lyme during pregnancy or who have been diagnosed with PTLDS/Chronic Lyme.

Yes ↓

Are you still experiencing active symptoms of PTLDS/Chronic Lyme? — No → Unfortunately, you are not eligible. We are only recruiting patients in our PTLDS cohort who are currently experiencing symptoms.

Yes ↓

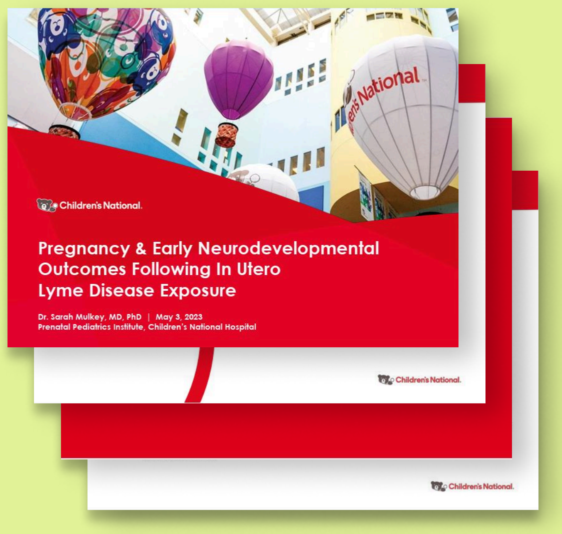
You might be eligible for our Post-Treatment Lyme Disease Syndrome cohort, depending on when you were treated for your initial Lyme infection and the duration of your PTLDS symptoms.

Please contact a member of our research team at **cnhlymestudy@gmail.com** or complete the form at **www.redcap.link/CNHLYME**

Children's National.

Inclusion Exclusion Flowchart

This flowchart, available as both a JPG and PDF, gives an at-a-glance summary of our inclusion and exclusion criteria for each of the study's two cohorts. This can be used to help screen your patients or clients for initial eligibility in our study. If they are eligible, please refer them to www.redcap.link/CNHLYME to complete the online screener.


Children's National.

Pregnancy & Early Neurodevelopmental Outcomes Following In Utero Lyme Disease Exposure

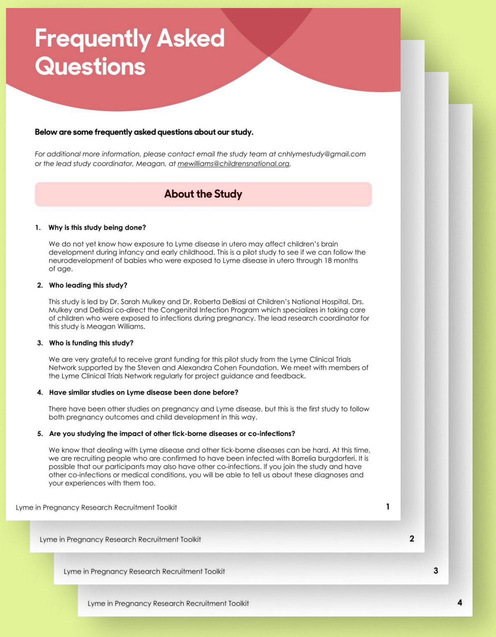
Dr. Sarah Mulkey, MD, PhD | May 3, 2023
Prenatal Pediatrics Institute, Children's National Hospital

Slides from Introductory Webinar (May 3, 2023)

These are the slides from Dr. Sarah Mulkey's webinar on May 3, 2023 which introduced the pilot study to stakeholders across the US and Canada. Please feel free to reference these slides for details about the pilot study, including:

- Study overview and aims
- Details about our two participant cohorts
- Study timeline and schedule of events

As a recipient of the Recruitment Toolkit, you may also download and share these slides with colleagues who were unable to attend the presentation live. Please cite this presentation as follows: Mulkey, SB. Pregnancy & Early Neurodevelopmental Outcomes Following In Utero Lyme Disease Exposure. Webinar. May 3, 2023. Accessed [Month Day, Year].


Frequently Asked Questions

Below are some frequently asked questions about our study.

For additional more information, please contact email the study team at cnhlymestudy@gmail.com or the lead study coordinator, Meagan, at mewilliams@childrensnational.org.

About the Study

1. **Why is this study being done?**

   We do not yet know how exposure to Lyme disease in utero may affect children's brain development during infancy and early childhood. This is a pilot study to see if we can follow the neurodevelopment of babies who were exposed to Lyme disease in utero through 18 months of age.

2. **Who leading this study?**

   This study is led by Dr. Sarah Mulkey and Dr. Roberta DeBiasi at Children's National Hospital. Drs. Mulkey and DeBiasi co-direct the Congenital Infection Program which specializes in taking care of children who were exposed to infections during pregnancy. The lead research coordinator for this study is Meagan Williams.

3. **Who is funding this study?**

   We are very grateful to receive grant funding for this pilot study from the Lyme Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation. We meet with members of the Lyme Clinical Trials Network regularly for project guidance and feedback.

4. **Have similar studies on Lyme disease been done before?**

   There have been other studies on pregnancy and Lyme disease, but this is the first study to follow both pregnancy outcomes and child development in this way.

5. **Are you studying the impact of other tick-borne diseases or co-infections?**

   We know that dealing with Lyme disease and other tick-borne diseases can be hard. At this time, we are recruiting people who are confirmed to have been infected with Borrelia burgdorferi. It is possible that our participants may also have other co-infections. If you join the study and have other co-infections or medical conditions, you will be able to tell us about these diagnoses and your experiences with them too.

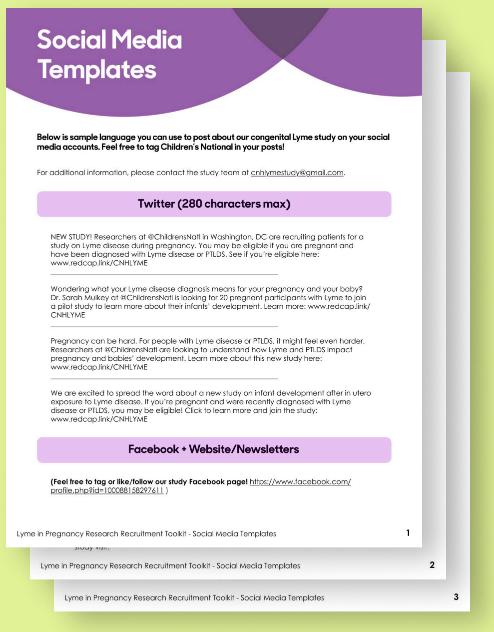
Lyme in Pregnancy Research Recruitment Toolkit 1
Lyme in Pregnancy Research Recruitment Toolkit 2
Lyme in Pregnancy Research Recruitment Toolkit 3
Lyme in Pregnancy Research Recruitment Toolkit 4

Lyme Study FAQs

In this document, we answered frequently asked questions about our Lyme study and organized them for you and your patients/clients to reference. Questions are organized into the following categories:

- About the Study
- Joining the Study
- Study Participation
- Study Procedures
- Other/Miscellaneous

If you have a question that is not listed in the FAQs document, please feel free to email your question to cnhlymestudy@gmail.com.


Social Media Templates

Below is sample language you can use to post about our congenital Lyme study on your social media accounts. Feel free to tag Children's National in your posts!

For additional information, please contact the study team at cnhlymestudy@gmail.com.

Twitter (280 characters max)

NEW STUDY! Researchers at @ChildrensNatl in Washington, DC are recruiting patients for a study on Lyme disease during pregnancy. You may be eligible if you are pregnant and have been diagnosed with Lyme disease or PTLDS. See if you're eligible here: www.redcap.link/CNHLYME

Wondering what your Lyme disease diagnosis means for your pregnancy and your baby? Dr. Sarah Mulkey at @ChildrensNatl is looking for 20 pregnant participants with Lyme to join a pilot study to learn more about their infants' development. Learn more: www.redcap.link/CNHLYME

Pregnancy can be hard. For people with Lyme disease or PTLDS, it might feel even harder. Researchers at @ChildrensNatl are looking to understand how Lyme and PTLDS impact pregnancy and babies' development. Learn more about this new study here: www.redcap.link/CNHLYME

We are excited to spread the word about a new study on infant development after in utero exposure to Lyme disease. If you're pregnant and were recently diagnosed with Lyme disease or PTLDS, you may be eligible! Click to learn more and join the study: www.redcap.link/CNHLYME

Facebook + Website/Newsletters

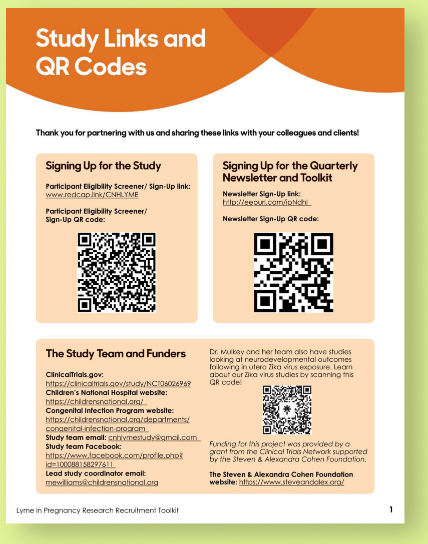
(Feel free to tag or like/follow our study Facebook page! https://www.facebook.com/profile.php?id=100088158297611)

Lyme in Pregnancy Research Recruitment Toolkit - Social Media Templates 1
Lyme in Pregnancy Research Recruitment Toolkit - Social Media Templates 2
Lyme in Pregnancy Research Recruitment Toolkit - Social Media Templates 3

Social Media Templates

Please post about our study on your website, blog, or social media pages! We would love your help spreading the word to other stakeholders and potential participants. Feel free to use these templates we have created for you, and don't forget to tag us in your posts!

We would love to see your posts about our study and may even highlight them in our newsletter. If you use our templates or have a different idea in mind, please share it with the team at cnhlymestudy@gmail.com.



Study Links and QR Codes

Thank you for partnering with us and sharing these links with your colleagues and clients!

Signing Up for the Study

Participant Eligibility Screener/ Sign-Up link: www.redcap.link/CNHLYME

Participant Eligibility Screener/ Sign-Up QR code:

Signing Up for the Quarterly Newsletter and Toolkit

Newsletter Sign-Up link: http://eepurl.com/ipNdhI

Newsletter Sign-Up QR code:

The Study Team and Funders

ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT06026969
Children's National Hospital website: https://childrensnational.org/
Congenital Infection Program website: https://childrensnational.org/departments/congenital-infection-program
Study team email: cnhlymestudy@gmail.com
Study team Facebook: https://www.facebook.com/profile.php?id=100088158297611
Lead study coordinator email: mewilliams@childrensnational.org

Dr. Mulkey and her team also have studies looking at neurodevelopmental outcomes following in utero Zika virus exposure. Learn about our Zika virus studies by scanning this QR code!

Funding for this project was provided by a grant from the Clinical Trials Network supported by the Steven & Alexandra Cohen Foundation.

The Steven & Alexandra Cohen Foundation website: https://www.steveandalex.org/

Lyme in Pregnancy Research Recruitment Toolkit 1

Study Links and QR Codes

This document includes all QR codes and websites related to the study for your easy reference. Links are organized into the following categories:

- **Signing Up for the Study**
- **Signing Up for the Quarterly Newsletter and Toolkit**
- **The Study Team and Funders**

Mulkey Laboratory
111 Michigan Ave NW, M3118
Washington, DC 20010-2916
ChildrensNational.org

Pregnant Volunteers Needed

Children's National

Children's National Hospital is looking for **pregnant volunteers** for a research study. You may be eligible if you have been diagnosed with **Lyme disease** during your current pregnancy or with **Post-Treatment Lyme Disease Syndrome (PTLDS)** in the past 3 years. You will be paid for your time.

Study Overview

We are enrolling pregnant volunteers with Lyme disease and/or PTLDS to follow their pregnancy and the neurodevelopment of their infants through age 18 months. If you join this study, we will collect information about you during and after pregnancy and monitor your baby's development. The study includes questionnaires, one fetal MRI and ultrasound, one infant MRI and ultrasound, two in-person neurology evaluations, and two blood draws.

Why Participate?

By participating in the study, you can help researchers, doctors, and families understand the impacts of Lyme disease during pregnancy. You can help us learn how to treat and protect future babies and children. After each study visit, you will have the unique opportunity to learn from a neurologist about your child's brain and development at no cost to you. You will be paid for your time at each study visit.

Funding for this project was provided by a grant from the Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation.

Why is This Study Being Done?

There are many questions about Lyme disease infection during pregnancy that have not yet been answered.

We are doing this study to learn about how Lyme disease exposure during pregnancy impacts babies' brain growth and neurodevelopment.

By participating in this study, you can help us learn how to treat and protect future babies and children.

Contact Us!

To learn more or join the study, scan the QR code or contact our study team!

Sarah Mulkey, M.D., Ph.D.
202-476-3388
cnhlymestudy@gmail.com
mewilliams@childrensnational.org

Help us learn how Lyme disease during pregnancy affects children and families.

Join a study or learn more at
lymeinpregnancyresearch.com

“I was just diagnosed with Lyme disease. Will that affect my baby?”

Join our study or learn more at
lymeinpregnancyresearch.com

Children's National

Pregnant Volunteers with Lyme Disease Needed for a Study

Lyme disease is the most common tick-borne illness in the United States.

We are doing a study to learn how Lyme disease during pregnancy affects babies' brain growth and development.

Travel is not required. The study is free to join. You will be paid for your time.

You may be eligible if you:

- ✓ Are pregnant
- ✓ Live in the U.S. or Canada
- ✓ Have been diagnosed with acute Lyme disease, chronic Lyme, or PTLDS during pregnancy

Please note: You do not need to live near Washington, DC to join. The study can be done remotely.

Participation includes:

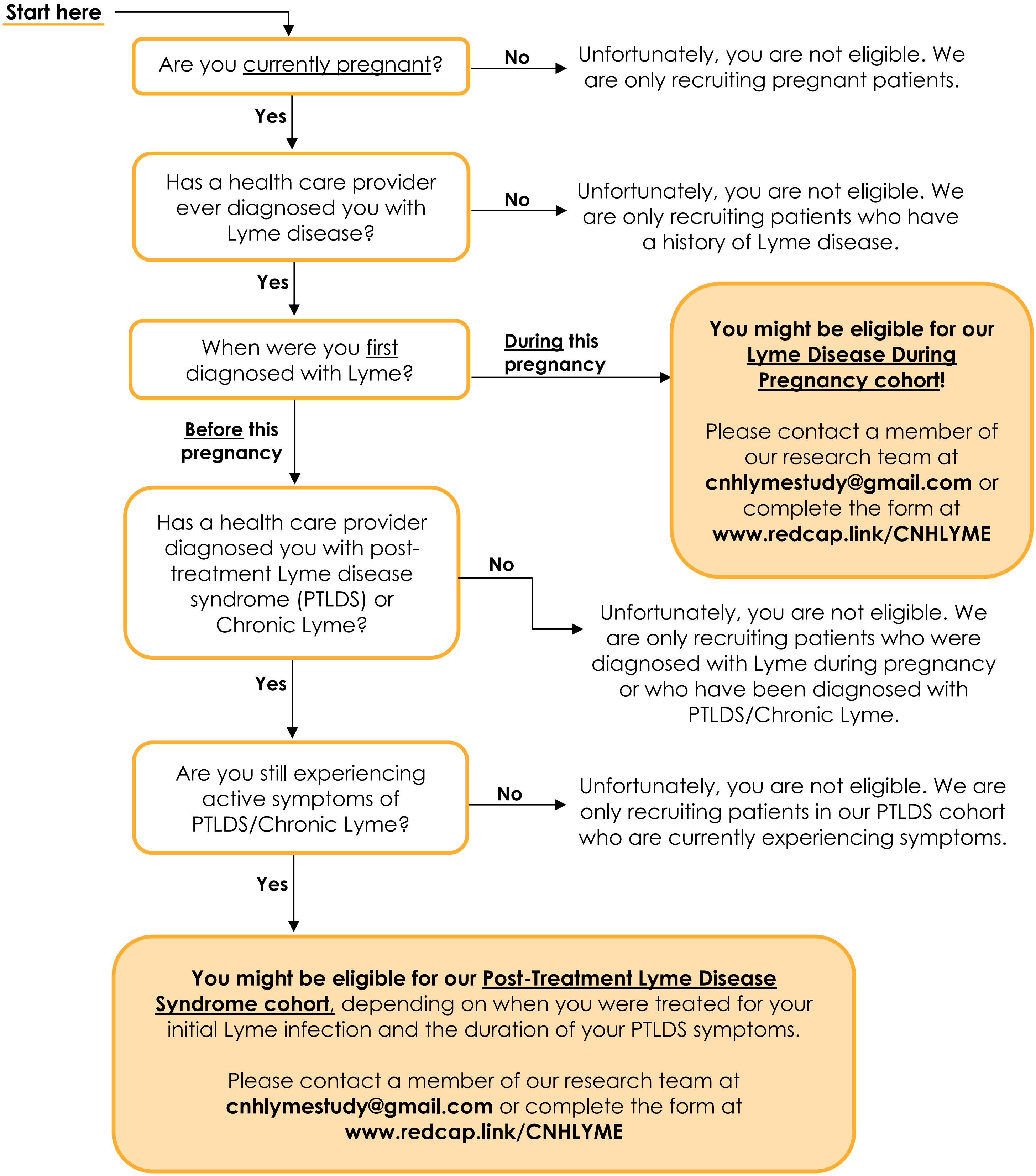
- **Pregnancy**
  Blood testing and imaging
  Questionnaires
  Optional interview
- **Delivery**
  Analysis of your placenta
- **Your child's first 18 months**
  Blood testing and imaging
  Questionnaires
  Developmental assessment
  Neurology appointments

Help us learn how to treat and protect babies and children exposed to Lyme disease during pregnancy.

To learn more or join the study:

- Call **(202) 476-3388**
- Email **cnhlymestudy@gmail.com**
- Visit our website at **lymeinpregnancyresearch.com**
- Scan the QR code above

Am I Eligible for the Congenital Lyme Disease Study?



Start here

Are you currently pregnant?

No → Unfortunately, you are not eligible. We are only recruiting pregnant patients.

Yes

Has a health care provider ever diagnosed you with Lyme disease?

No → Unfortunately, you are not eligible. We are only recruiting patients who have a history of Lyme disease.

Yes

When were you first diagnosed with Lyme?

During this pregnancy →

You might be eligible for our Lyme Disease During Pregnancy cohort!

Please contact a member of our research team at **cnhlymestudy@gmail.com** or complete the form at **www.redcap.link/CNHLYME**

Before this pregnancy

Has a health care provider diagnosed you with post-treatment Lyme disease syndrome (PTLDS) or Chronic Lyme?

No → Unfortunately, you are not eligible. We are only recruiting patients who were diagnosed with Lyme during pregnancy or who have been diagnosed with PTLDS/Chronic Lyme.

Yes

Are you still experiencing active symptoms of PTLDS/Chronic Lyme?

No → Unfortunately, you are not eligible. We are only recruiting patients in our PTLDS cohort who are currently experiencing symptoms.

Yes

You might be eligible for our Post-Treatment Lyme Disease Syndrome cohort, depending on when you were treated for your initial Lyme infection and the duration of your PTLDS symptoms.

Please contact a member of our research team at **cnhlymestudy@gmail.com** or complete the form at **www.redcap.link/CNHLYME**

Children's National

Children's National.

Pregnancy & Early Neurodevelopmental Outcomes Following In Utero Lyme Disease Exposure

Dr. Sarah Mulkey, MD, PhD | May 3, 2023
Prenatal Pediatrics Institute, Children's National Hospital

Outline

- Introduction
- Study Details
- Partner With Us!
- Questions

Children's National.

Introduction

Study Team

Sarah Mulkey
MD, PhD (she/her)

Prenatal and Neonatal Neurologist, Division of Prenatal Pediatrics

Co-Director, Congenital Infection Program

Roberta DeBiasi
MD, MS (she/her)

Chief, Division of Pediatric Infectious Diseases

Co-Director, Congenital Infection Program

Meagan Williams
MSPH, CCRC (she/her)

Clinical Research Coordinator, Divisions of Pediatric Infectious Diseases and Prenatal Pediatrics

Children's National.

Above: Children's National Hospital, Washington, DC

Congenital Infection Program

The Congenital Infection Program specializes in evaluating and researching outcomes of children with antenatal exposure to infectious agents.

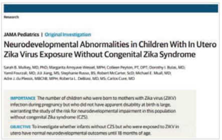
SHOTS - HEALTH NEWS

5 years later, researchers assess how children exposed to Zika are developing

December 27, 2021 · 5:00 AM ET

Heard on All Things Considered

Selena Simmons-Duffin



Research

JAMA Pediatrics | Original Investigation

Neurodevelopmental Abnormalities in Children With In Utero Zika Virus Exposure Without Congenital Zika Syndrome

Sarah B. Mulkey, MD, PhD; Margarita Arroyave-Wessel, MPH; Colleen Peyton, PT, DPT; Dorothy I. Bulas, MD; Yamil Fourzali, MD; JiJi Jiang, MS; Stephanie Russo, BS; Robert McCarter, ScD; Michael E. Msall, MD; Adre J. du Plessis, MBChB, MPH; Roberta L. DeBiasi, MD, MS; Carlos Cure, MD

IMPORTANCE The number of children who were born to mothers with Zika virus (ZIKV) infection during pregnancy but who did not have apparent disability at birth is large, warranting the study of the risk for neurodevelopmental impairment in this population without congenital Zika syndrome (CZS).

OBJECTIVE To investigate whether infants without CZS but who were exposed to ZIKV in utero have normal neurodevelopmental outcomes until 18 months of age.

Congenital Infection Program

Contact number | 202-476-7409

One-of-a-Kind Program

We are one of the first comprehensive congenital infection programs in the country, dedicated to providing care during and after your pregnancy.

When you are pregnant, your greatest priority is protecting the health of your baby. A congenital infection is caused by a virus or bacteria. The infection is passed to the baby during pregnancy or may be in the birth canal during delivery.

If you are concerned about a congenital infection and wonder whether your child could be affected, turn to the experts in the Congenital Infection Program at Children's National Hospital.

Top left image: NPR article highlighting the Congenital Infection Program team

Bottom left image: Publication by Mulkey et al. in JAMA Pediatrics (2020)

Right image: Congenital Infection Program website

iStock

Lyme Disease and Pregnancy

There is some scientific agreement that *B. burgdorferi* can be vertically transmitted to a developing fetus and may cause congenital infection.

However, to date, no studies have systematically investigated pregnancy and long-term child neurodevelopment outcomes following in utero exposure to *B. burgdorferi*.

New Study: Now Recruiting!

We are conducting a <u>pilot study</u> to assess feasibility of evaluating **outcomes of pregnancies affected by Lyme disease infection** and the brain development of **fetuses and children who were exposed to Lyme disease in utero**.

Volunteers Needed

Children's National Hospital is looking for **<u>pregnant volunteers who have been diagnosed with Lyme disease during their current pregnancy.</u>** You will be paid for your time.

Study Overview:

We are enrolling pregnant volunteers with Lyme disease to follow their pregnancy and the neurodevelopment of their infants through age 18 months. If you join this study, we will collect information about you during and after pregnancy and monitor your baby's development. The study includes questionnaires, one fetal MRI and ultrasound, one infant MRI and ultrasound, two in-person neurology evaluations, and two blood draws.

Why participate?

By participating in the study, you can help researchers, doctors, and families understand the impacts of Lyme disease during pregnancy. You can help us learn how to treat and protect future babies and children. After each study visit, you will have the unique opportunity to learn from a neurologist about your child's brain and development at no cost to you. You will be paid for your time at each study visit.

Why is this study being done?

There are many questions about Lyme disease infection during pregnancy that have not yet been answered.

We are doing this study to learn about how Lyme disease during pregnancy impacts babies' brain growth and neurodevelopment.

Contact Us!

To learn more or join the study, scan the QR code or contact our study team!

Sarah Mulkey, M.D., Ph.D.
202-476-3388
mewilliams@childrensnational.org

$$$ Funding for this project was provided by a grant from the Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation.

Study Details

Overview

We will recruit participants with Lyme disease or Post-Treatment Lyme Disease Syndrome **during pregnancy** and follow their infants' development **through 18 months** of age.

This pilot study will be the <u>first study</u> to evaluate the long-term impact of Lyme disease exposure on pregnancy, brain development, and childhood neurodevelopment.

Study Aims

Assess child neurodevelopment	1	To determine whether infants exposed to *B. burgdorferi* in utero have abnormal neurodevelopmental outcomes to age 18 months
Evaluate brain abnormalities	2	To evaluate whether there are abnormalities in the fetal and neonatal brains of *B. burgdorferi*-exposed fetuses and infants
Assess pregnancy outcomes	3	To assess pregnancy outcomes associated with gestational exposure to Lyme disease based on the timing of Lyme disease exposure, symptom onset, and treatment

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Participants

- <u>**All**</u> participants must be pregnant, >18 years of age, capable of comprehending the study, and available for long-term follow-up requirements*

*Note: Travel to Children's National Hospital for a fetal and infant MRI is <u>strongly</u> <u>preferred</u>, but <u>not</u> required. Participants will be excluded from the MRI portion of the study if they have health issues or metallic implant that precludes them from undergoing MRI.

Cohort #1:
Lyme disease diagnosis during pregnancy

Cohort #2:
Post-Treatment Lyme Disease Syndrome during pregnancy

Two Cohorts

Cohort #1:
Lyme disease diagnosis during pregnancy

About Cohort #1:
- Currently <u>**pregnant**</u>
- Meet CDC criteria for clinical/ laboratory diagnosis of any stage of <u>**Lyme disease occurring during any trimester of current pregnancy**</u>

Cohort #2:
Post-Treatment Lyme Disease Syndrome during pregnancy

About Cohort #2:
- Currently <u>**pregnant**</u>
- <u>**Completed treatment for any stage of Lyme disease between 6 months and 3 years ago**</u>
  - Lyme disease previously diagnosed using CDC criteria for clinical/laboratory diagnosis
- Currently with <u>**active symptoms**</u> attributed to clinician-diagnosed Post-Treatment Lyme Disease Syndrome (PTLDS) or Chronic Lyme

Two Cohorts

Cohort #1:
Lyme disease diagnosis during pregnancy

About Cohort #1:
- Currently **pregnant**
- Meet CDC criteria for clinical/ laboratory diagnosis of any stage of **Lyme disease occurring during any trimester of current pregnancy**

Cohort #2:
Post-Treatment Lyme Disease Syndrome during pregnancy

About Cohort #2:
- Currently **pregnant**
- **Completed treatment for any stage of Lyme disease between 6 months and 3 years ago**
  - Lyme disease previously diagnosed using CDC criteria for clinical/laboratory diagnosis
- Currently with **active symptoms** attributed to clinician-diagnosed Post-Treatment Lyme Disease Syndrome (PTLDS) or Chronic Lyme

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Study Timeline

Pregnancy (enrollment + one in-person visit, optional qualitative interview)

Delivery (data sharing with birth hospital, placental pathology)

Infancy (two in-person visits, three online visits)

Ongoing: Monitoring of clinical and demographic factors that may impact outcomes (Lyme/PTLDS, medical history, mental health, nutrition, SES, etc.)

Schedule of Events: Pregnancy

PREGNANCY	DELIVERY	INFANCY
MRI and ultrasound (2nd or 3rd trimester) Antibody testing and cytokine panel Monitoring of Lyme/ PTLDS, pregnancy, and fetal growth ***Optional:*** Qualitative interview	Delivery hospital shares: • newborn records, including infant length and weight • labor and delivery records • placental pathology reports Additional analysis of placenta	Infant brain MRI, cranial ultrasound, neurological exams Antibody testing and cytokine panel Ongoing monitoring of infant growth and neurodevelopment (ASQ, WIDEA, AIMS)

ONGOING: Monitoring of clinical and demographic factors that may impact outcomes (SES, nutrition, medical history, Lyme/PTLDS history, mental health, etc.)

Schedule of Events: Delivery

PREGNANCY	DELIVERY	INFANCY
MRI and ultrasound (2nd or 3rd trimester) Antibody testing and cytokine panel Monitoring of Lyme/ PTLDS, pregnancy, and fetal growth ***Optional:*** Qualitative interview	Delivery hospital shares: • newborn records, including infant length and weight • labor and delivery records • placental pathology reports Additional analysis of placenta	Infant brain MRI, cranial ultrasound, neurological exams Antibody testing and cytokine panel Ongoing monitoring of infant growth and neurodevelopment (ASQ, WIDEA, AIMS)

ONGOING: Monitoring of clinical and demographic factors that may impact outcomes (SES, nutrition, medical history, Lyme/PTLDS history, mental health, etc.)

Schedule of Events: Infancy

PREGNANCY	DELIVERY	INFANCY
MRI and ultrasound (2nd or 3rd trimester) Antibody testing and cytokine panel Monitoring of Lyme/ PTLDS, pregnancy, and fetal growth *Optional:* Qualitative interview	Delivery hospital shares: • newborn records, including infant length and weight • labor and delivery records • placental pathology reports Additional analysis of placenta	Infant brain MRI, cranial ultrasound, neurological exams Antibody testing and cytokine panel Ongoing monitoring of infant growth and neurodevelopment (ASQ, WIDEA, AIMS)

ONGOING: Monitoring of clinical and demographic factors that may impact outcomes (SES, nutrition, medical history, Lyme/PTLDS history, mental health, etc.)

Partner With Us!

We Need Your Help!

If you…

- know a pregnant person who might be eligible to participate in this study
- have colleagues whose clients might be pregnant with Lyme disease or PTLDS
- are interested in sharing this research with your organization's audience or stakeholders

Please refer them to our research team!

If you have patients who may be eligible, please contact us!

Sarah Mulkey, MD, PhD (PI):
sbmulkey@childrensnational.org

Research team:
Meagan Williams, MSPH:
mewilliams@childrensnational.org
cnhlymestudy@gmail.com

Tip: Take a photo of this slide to reference later!

Recruitment Toolkit

If you are interested in helping our team find study participants, we made you a **Recruitment Toolkit**!

The Toolkit includes our study recruitment flyer, social media templates, important links, FAQs, and more to help you share information about our study with your patients, clients, and colleagues!

Link on the next slide →

Stay Connected

Scan the QR code or visit the website below to stay connected with our research team!

Make sure to select "**Yes**" if you want access to our Recruitment Toolkit!

http://eepurl.com/ipNdhl

Children's National.

Questions?

- **Email the team**: cnhlymestudy@gmail.com
- **Stay connected**: Scan the QR code to sign up for our email newsletter!
- **Thank you to our funders!** This study was funded by a grant from the Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation.

Frequently Asked Questions

Below are some frequently asked questions about our study.

For additional more information, please contact email the study team at cnhlymestudy@gmail.com or the lead study coordinator, Meagan, at mewilliams@childrensnational.org.

About the Study

1. **Why is this study being done?**

   We do not yet know how exposure to Lyme disease in utero may affect children's brain development during infancy and early childhood. This is a pilot study to see if we can follow the neurodevelopment of babies who were exposed to Lyme disease in utero through 18 months of age.

2. **Who leading this study?**

   This study is led by Dr. Sarah Mulkey and Dr. Roberta DeBiasi at Children's National Hospital. Drs. Mulkey and DeBiasi co-direct the Congenital Infection Program which specializes in taking care of children who were exposed to infections during pregnancy. The lead research coordinator for this study is Meagan Williams.

3. **Who is funding this study?**

   We are very grateful to receive grant funding for this pilot study from the Lyme Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation. We meet with members of the Lyme Clinical Trials Network regularly for project guidance and feedback.

4. **Have similar studies on Lyme disease been done before?**

   There have been other studies on pregnancy and Lyme disease, but this is the first study to follow both pregnancy outcomes and child development in this way.

5. **Are you studying the impact of other tick-borne diseases or co-infections?**

   We know that dealing with Lyme disease and other tick-borne diseases can be hard. At this time, we are recruiting people who are confirmed to have been infected with Borrelia burgdorferi. It is possible that our participants may also have other co-infections. If you join the study and have other co-infections or medical conditions, you will be able to tell us about these diagnoses and your experiences with them too.

Joining the Study

1. **Am I eligible to join this study?**

   We are looking for participants who are:
   ☐ Pregnant (any trimester)
   ☐ Over 18 years old
   ☐ Living in the United States or Canada
   And who meet ONE of the following criteria:
   ☐ Were bitten by a tick and meet CDC criteria for clinical/laboratory diagnosis of Lyme disease during your current pregnancy

   OR

   ☐ Completed treatment for clinically diagnosed Lyme disease (using CDC criteria for clinical/laboratory diagnosis) between 6 months and 5 years ago ***AND*** currently have active symptoms attributed to clinically diagnosed Post-Treatment Lyme Disease Syndrome (PTLDS) or Chronic Lyme.

   To see if you can join the study, please reach out to our team at cnhlymestudy@gmail.com. We will review your medical information and let you know if you can join at this time.

2. **What labs are required to show that I was clinically diagnosed with Lyme/PTLDS?**

   For this pilot study, we are enrolling patients who meet the strictest definition of having a Lyme disease diagnosis per CDC guidelines. This means having a clinician-diagnosed erythema migrans (EM) or "bullseye" rash, and/or positive two-tiered testing from an FDA-approved lab.

   We know that getting a clinical Lyme diagnosis is a multi-step process and that FDA-approved diagnostic tests may not capture every patient with Lyme. For this pilot study, we cannot include labs that have not received FDA approval. We hope that if the results of our pilot study show that it is possible to enroll patients with Lyme disease and PTLDS, we can then get more funding to include other people with other types of positive tests that are not currently FDA-approved.

3. **What if I have/have not decided to treat my Lyme during pregnancy? Can I still join?**

   Yes, you may participate as long as you fulfill the other eligibility requirements. We will collect information about your treatment during the study.

4. **My child is X years old and I think they have been affected by Lyme disease. Can I enroll us in the study?**

   Thank you so much for your interest. For this pilot study, we are only recruiting people who are currently pregnant. This is so we can collect important information such as fetal development and any abnormalities in the placenta. Future work after this pilot study may include other groups of participants, such as those with older children. To keep in touch with our study team and learn about new opportunities, please sign up for our Quarterly Newsletter.

5. **I was diagnosed with Lyme disease X years ago and was treated. I am now pregnant and am not experiencing any symptoms. Can I enroll in the study?**

   If you were fully treated for Lyme disease before becoming pregnant and have not had Lyme /PTLDS symptoms during pregnancy, you are not eligible for this current study.

6. **If I join, how long will I be in the study?**

   You will join the study during any trimester of pregnancy. You will be in the study until your child is 18 months old. You are free to leave the study at any time.

7. **How many other people are in this study?**

   We are hoping to recruit 40 pregnant people and their infants for this study. We hope that future studies will include additional cohorts and a larger sample size.

Study Participation

1. **Do I have to travel to Washington, DC?**

   You do not have to come to Washington, DC to join the study. We offer a "Remote only" option for participants who cannot travel. Either way, most study visits are done online.

   We would like to learn as much as we can about you and your baby. You may choose to come to Children's National Hospital for one or two study visits so we can get an MRI and ultrasound of your baby's brain. These parts of the study are very important in helping us learn about your baby's development. To help make it easier, we will pay for your travel up to a certain amount. Please contact mewilliams@childrensnational.org if you have questions.

   If you are not able to come to one or more of these in-person visits, you can still join this study and do all of the study tasks except for the MRI and ultrasound.

2. **What will happen in this study?**

   We will study your child's development until they are 18 months old. At each study visit, we will learn about your Lyme/PTLDS experience and get other information from you using online surveys.

   During Pregnancy: We will do a blood test, do a fetal MRI and ultrasound during your 2nd or 3rd trimester, and collect information from you about your Lyme/PTLDS history. You may also choose to share your experience about Lyme and pregnancy with our research team in a qualitative interview during your 3rd trimester.

   After Delivery: When your baby is born, we will collect information about your labor and delivery and your baby. We will also collect and analyze your placenta for any important changes.

   During Infancy: Your baby will have a brain MRI and ultrasound when they are between 2-6 weeks old. We will also test your baby's blood for Lyme disease. You will meet with our neurologist using telehealth multiple times throughout the study to review your baby's health and development.

   You will be paid for your time at each in-person and online study visit.

3. **Will you tell me how my child is doing after you evaluate them?**

   Of course! After each study visit you will get a report from our study team with the results of your surveys and your baby's developmental exam.

4. **Will you talk to my other doctors or health care providers? Will they know I am in this study?**

   As part of this study, we will ask that you and/or your doctors share some information with us so we can learn about your and your baby's medical history. We will also ask your birth hospital to share information with us after your baby is born. <u>We will not contact your doctors or health care providers, or collect medical information about you or your baby, without clear permission from you</u>. If you'd like, you may tell your and your child's providers that you are participating in this study to follow your child's neurodevelopment.

5. **What kinds of surveys will I complete? What if I want to share more about my experience?**

   You will do surveys about your and your baby's medical history and nutrition, your pregnancy history, demographic information, and more. Once your baby is 2 months old, you will also complete a neurodevelopmental screening survey at each study visit.

   All study participants are invited to participate in an optional interview with a member of our research team. This semi-structured interview will help us learn more about your experiences navigating Lyme disease or PTLDS/Chronic Lyme during pregnancy.

6. **Will I be paid for participating in this study?**

   Yes. When you enroll in the study, you will receive a Clincard, which works like a debit card. You will receive compensation for each online and in-person study visit. The payment will be automatically loaded to your card after you complete each study visit.

Study Participation

1. **What parts of my baby's development will you be looking at in this study?**

   We will be looking at a wide range of neurodevelopmental outcomes. For example, we will assess age-appropriate measures of communication, movement (fine and gross motor), social cognition, and problem-solving skills.

   We do not have an evaluation plan for conditions that tend to show up later in childhood, like autism. However, we hope that with more funding we may be able to follow these children longer than 18 months, such as through toddlerhood and early childhood. In this case, we will assess additional areas of development appropriate for older ages.

2. **What will the MRI be looking for?**

   Both the fetal MRI and the newborn MRI will be done to find any structural abnormalities to the developing brain. For example, we will measure brain volume, and do quantitative analysis to look at gray and white matter, to determine if the brain is developing differently than we would expect a healthy brain to develop.

3. **I would like to be a "Remote only" participant. Can I get the MRI and/or ultrasound done somewhere else?**

   All MRI and ultrasound imaging needs to be completed at Children's National Hospital in Washington, DC in order for the study to pay for it. If another institution does any clinical imaging (for example, if your obstetrician performs a fetal ultrasound) you may feel free to share those records with us. However, you will be responsible for the cost of any imaging that occurs outside of Children's National.

4. **Will any special studies be done on the placentas?**

   We will do special testing on the placenta to look for the *Borrelia burgdorferi* spirochete and other evidence of placental tissue abnormality or signs of inflammation.

5. **Are you collecting cord blood for this study?**

   No, we are not collecting cord blood for this pilot study.

Other/Miscellaneous

1. **What will happen if you find that a baby or placenta has been infected with Lyme disease?**

   While our study is looking at infant neurodevelopment and not at Lyme treatment, it is important to us that you get the best care and treatment possible for your Lyme disease. If we feel that you or your baby would benefit from clinical evaluation or follow-up beyond the scope of our study, we may make a referral to a specialized doctor in your area. This may include the Congenital Infection Program at Children's National Hospital for any infected babies or children in DC, Maryland, or Virginia.

2. **What will happen in the event of a miscarriage or stillbirth?**

   We certainly hope that none of our participants experience a miscarriage or stillbirth. If this does happen, we will work with the obstetrician, maternal-fetal medicine doctor, and/or birth hospital to obtain fetal tissues and the placenta for additional Lyme-related testing. Our consent form goes into further detail about this process.

FAQs for Providers

1. **I have a patient/participant who I think might be eligible. Can I share their contact information with you?**

   With their permission, you may email their name and contact information to our study team at mewilliams@childrensnational.org. You may also share our study flyer with them or invite them to fill out the eligibility screener at www.redcap.link/CNHLYME.

2. **I'm interested in collaborating with you on this study. What can I do?**

Thank you very much for your interest! We are very grateful to our collaborators for making this study possible.

Here are some ways you can help us:

- Please spread the word about our study! Feel free to post our flyer or postcards [MW1] in your office or waiting room, on your website, or other places where your patients and/or colleagues may find it. You may use our Social Media Templates[MW2] for sample language for posting on social media, blogs or newsletters, or your website. If you need access to any of these documents or need something else, please email mewilliams@childrensnational.org.

- If you know someone who may be interested in joining the study, please invite them to complete the interest form or eligibility screener or email cnhlymestudy@gmail.com for more information.

- Sign up to get our Quarterly Newsletter for updates from our study team.

- We hope that after this pilot study, we can obtain additional funding to conduct a larger multi-center study. If you are interested in exploring the possibility of joining our multi-center study as a study site, please email the study coordinator at mewilliams@childrensnational.org.

If you have other ideas on how we can collaborate, please email Meagan at mewilliams@childrensnational.org or the study team at cnhlymestudy@gmail.com. We look forward to hearing from you!

[MW1]link

[MW2]link

Social Media Templates

Below is sample language you can use to post about our congenital Lyme study on your social media accounts. Feel free to tag Children's National in your posts!

For additional information, please contact the study team at cnhlymestudy@gmail.com.

Twitter (280 characters max)

NEW STUDY! Researchers at @ChildrensNatl in Washington, DC are recruiting patients for a study on Lyme disease during pregnancy. You may be eligible if you are pregnant and have been diagnosed with Lyme disease or PTLDS. See if you're eligible here: www.redcap.link/CNHLYME

Wondering what your Lyme disease diagnosis means for your pregnancy and your baby? Dr. Sarah Mulkey at @ChildrensNatl is looking for 20 pregnant participants with Lyme to join a pilot study to learn more about their infants' development. Learn more: www.redcap.link/CNHLYME

Pregnancy can be hard. For people with Lyme disease or PTLDS, it might feel even harder. Researchers at @ChildrensNatl are looking to understand how Lyme and PTLDS impact pregnancy and babies' development. Learn more about this new study here: www.redcap.link/CNHLYME

We are excited to spread the word about a new study on infant development after in utero exposure to Lyme disease. If you're pregnant and were recently diagnosed with Lyme disease or PTLDS, you may be eligible! Click to learn more and join the study: www.redcap.link/CNHLYME

Facebook + Website/Newsletters

(Feel free to tag or like/follow our study Facebook page! https://www.facebook.com/profile.php?id=100088158297611)

ANNOUNCEMENT: New Study on Lyme Disease During Pregnancy

Children's National Hospital is looking for **pregnant volunteers** who have been diagnosed with Lyme disease during their current pregnancy or who have been diagnosed with Post-Treatment Lyme Disease Syndrome (PTLDS) within the past 3 years.

- **Study Overview:** Dr. Sarah Mulkey and the research team at Children's National are conducting a pilot study to learn about how Lyme disease exposure during pregnancy impacts babies' brain growth and neurodevelopment.
- **Am I Eligible?** You may be eligible if you are CURRENTLY pregnant and either (1) have been diagnosed with Lyme disease during their current pregnancy, ***OR*** (2) have been diagnosed with Lyme disease between 6 months and 3 years ago ***AND*** currently have active symptoms clinically attributed to post-treatment Lyme disease syndrome (PTLDS) or Chronic Lyme.
- **Study Procedures:** If you join this study, we will collect information about you during and after pregnancy and monitor your baby's development. The study includes questionnaires, one fetal MRI and ultrasound, one infant MRI and ultrasound, two in-person neurology evaluations, and two blood draws at no cost to you. You will have the opportunity to learn from a neurologist about your child's brain and development after each study visit.
- **Compensation:** You will be paid for your time at each study visit.

To learn more and see if you're eligible, visit www.redcap.link/CNHLYME.

Have you recently been diagnosed with Lyme disease while pregnant?

There are many questions about Lyme disease infection during pregnancy that have not yet been answered.

Dr. Sarah Mulkey at Children's National Hospital in Washington, DC, USA is looking for 20 pregnant participants with Lyme to join a pilot study to learn about how Lyme disease exposure during pregnancy impacts babies' brain growth and neurodevelopment.

By participating in the study, you can help researchers, doctors, and families understand the impacts of Lyme disease during pregnancy.

Learn more about the study and sign up here: www.redcap.link/CNHLYME

[Organization name] is excited to excited to spread the word about a new study on infant development after in utero exposure to Lyme disease!

If you're pregnant and were recently diagnosed with Lyme disease or post-treatment Lyme disease syndrome (PTLDS), you may be eligible to participate in a new pilot study led by Dr. Sarah Mulkey at Children's National Hospital.

The research team is currently enrolling pregnant volunteers to follow their pregnancies and the neurodevelopment of their infants through age 18 months. The study includes questionnaires, one fetal MRI and ultrasound, one infant MRI and ultrasound, two in-person neurology evaluations, two blood draws, and personalized feedback about your child's development by a child neurologist at no cost to you. You will be paid for your time at each study visit.

By participating in this study, you can help researchers and providers learn how to better treat and protect future babies and children exposed to Lyme disease in utero.

Click to learn more about the study and see if you're eligible: www.redcap.link/CNHLYME

Dr. Mulkey Bios

Short Bio:

Sarah Mulkey, M.D., Ph.D.
- Prenatal-Neonatal Neurologist
- Director, Fetal-Neonatal Neurology Clinical and Research Fellowship
- Co-Lead, Congenital Infection Program, Prenatal Pediatrics Institute, Children's National Hospital
- Associate Professor, Departments Neurology and Pediatrics, The George Washington University School of Medicine and Health Sciences

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Long Bio:

Sarah Mulkey, M.D., Ph.D., is a Prenatal-Neonatal Neurologist in the Prenatal Pediatrics Institute at Children's National Hospital and an Associate Professor of Neurology and Pediatrics at The George Washington University School of Medicine and Health Sciences in Washington, DC. She is the Co-Director of the Congenital Infection Program and the Director of the Fetal Neurology Fellowship at Children's National Hospital in Washington, DC.

Dr. Mulkey's research interests include brain injury in the fetus and newborn, congenital infectious encephalopathies including Zika virus, and evaluation of neurodevelopmental outcomes. She has contributed to national guidelines for the care of infants exposed to infection during pregnancy. Her research in this area focuses on neuroimaging and long-term neurodevelopment of infants exposed to congenital infections such as Zika virus, COVID-19, and Lyme disease. Dr. Mulkey is an active member of the Society for Pediatric Research, the Child Neurology Society, and the Newborn Brain Society.

Study Links and QR Codes

Thank you for partnering with us and sharing these links with your colleagues and clients!

Signing Up for the Study

Participant Eligibility Screener/ Sign-Up link:
www.redcap.link/CNHLYME

Participant Eligibility Screener/ Sign-Up QR code:

Signing Up for the Quarterly Newsletter and Toolkit

Newsletter Sign-Up link:
http://eepurl.com/ipNdhI

Newsletter Sign-Up QR code:

The Study Team and Funders

ClinicalTrials.gov:
https://clinicaltrials.gov/study/NCT06026969
Children's National Hospital website:
https://childrensnational.org/
Congenital Infection Program website:
https://childrensnational.org/departments/congenital-infection-program
Study team email: cnhlymestudy@gmail.com
Study team Facebook:
https://www.facebook.com/profile.php?id=100088158297611
Lead study coordinator email:
mewilliams@childrensnational.org

Dr. Mulkey and her team also have studies looking at neurodevelopmental outcomes following in utero Zika virus exposure. Learn about our Zika virus studies by scanning this QR code!

Funding for this project was provided by a grant from the Clinical Trials Network supported by the Steven & Alexandra Cohen Foundation.

The Steven & Alexandra Cohen Foundation website: https://www.steveandalex.org/