



RESEARCH CONSENT FORM

Protocol Title: Comparative effectiveness and complications of intravenous ceftriaxone compared with oral doxycycline in Lyme meningitis

Principal Investigator: Lise Nigrovic, MD MPH

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

Please check one of the following:

You are an adult participant in this study.

You are the parent or guardian granting permission for a child in this study.

If the participant is a child the use of "you" refers to "your child"

Summary of Important Information

We are asking you to participate in this research study. Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not impact the clinical care you receive at Boston Children's Hospital.

In this research study we want to learn more about Lyme meningitis. We want to understand how different antibiotics impact how quickly your symptoms resolve.

It is important to consider reasons why you would or would not want to participate in this research.



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If you decide to join this research study, the following things will happen: We will collect information about your current symptoms and treatment preferences. We will collect information about your symptoms daily for 30 days and then measure your overall health in 6 weeks and 6 months. Your clinical care will be decided upon by your doctors using their best judgement and in consultation with you. **This study will not affect in any way how you are treated for Lyme meningitis. We seek simply to learn how quickly your treatment works for you.**

The most important risk is accidental disclosure of confidential medical information. Many measures have been taken to prevent this risk.

The most important potential benefits to know about are: Participation in this study will not benefit you directly. Participation will inform the best treatment for children with Lyme meningitis in the future.

It will take you about 6 months to complete this study. During this time, we will ask you to complete brief symptom surveys daily until your symptoms resolve and then to complete phone follow-up 6 week and 6 months after enrollment.

Your clinical care will be covered by your health insurer as your treatment will not change by taking part in this research. You will receive up to \$110 in gift cards for the completion of the study activities.

How are individuals selected for this research study?

You are being asked to participate in this research study because you have Lyme meningitis.

Why is this research study being conducted?

The goal of this research is to understand whether oral doxycycline works about as well as IV ceftriaxone in children with Lyme meningitis.

Who is conducting this research study, and where is it being conducted?

A grant from the National Institute of Allergy and Infectious Diseases (N.I.A.I.D.) will provide funding for this study.

How many people will participate in this research study?

Approximately 250 people will take part in this study at 20 different hospitals and medical facilities, including approximately 20 people at Boston Children's Hospital.

What do I have to do if I am in this research study?

You will participate in this study for 6 months. Participation in the study will not require you to return to Boston Children's Hospital. During your time on the study, the following things will happen:

- Today, research staff will ask you for information about your background, medical history as well as current symptoms related to Lyme disease. We will review your medical record to determine what medications you are taking. The research team will also ask you



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few questions about your Lyme meningitis treatment preferences and your overall health using the Pediatric Quality of Life survey

- You will be asked to complete an electronic daily symptom report (called the Pediatric Lyme Meningitis Symptom Measurement Instrument) and a medication compliance survey until your symptoms resolve. Completion of the survey will only take a few minutes each day.
- We will contact you electronically today as well as 6 weeks and 6 months from enrollment to complete the Pediatric Quality of Life Survey
- 6 weeks after enrollment, the study team at Rhode Island Hospital may contact you by telephone to ask you a few questions about your Lyme meningitis treatment preferences. Children older than 8 years of age will be encouraged to participate in these interviews. At this time, a trained interviewer will ask you open-questions to help the research team better understand your experiences with Lyme meningitis treatment.
- If your doctor diagnoses facial palsy (i.e. facial droop) as part of your Lyme meningitis, we will measure time to resolution using the House-Brackmann Facial Paralysis scale. To apply this scale, we require weekly full-face photo documentation for the first 6 weeks and then monthly until your facial palsy resolves or the study ends at 6 months.
- Study schedule:

Study Visit Timeline	Visit 1 Enrollment	Day 1 - 30	6 weeks	6 months	Payment
Consent /Assent	X				
Medical history	X				
Baseline preferences	X				
Quality of Life Questionnaire	X		X	X	\$10 x 3 surveys
Symptom survey	X	X			\$1 per response
Qualitative interview (telephone call)			X		\$25 x 1
Facial photo if you have facial palsy, weekly until resolution	X	X	X		\$5 per photo set until resolution



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What are the risks of this research study? What could go wrong?

Study participation will not impact the care you will receive for Lyme meningitis. The major risk of participation will be accidental disclosure of confidential medical information. All available measures will be taken to prevent this disclosure.

Another possible risk is if questions asked in the telephone interview cause emotional distress. This unlikely because most children with Lyme meningitis recover without problems, but it is possible that the interview may cause strong emotions based on your course.

What are the benefits of this research?

Being in this research may not help you right now. When we finish the research, we hope that we will know more about antibiotic treatment for Lyme meningitis. This may help other children and adults with Lyme meningitis in the future.

Will I receive my study results?

You will not receive your individual study results. If you would like, we can provide access to the published study results after completion.

Will my samples/information be used for research in the future?

Identifiable private information collected from you during this study may be used for future research studies or shared with other researchers for future research. The identifiable private information may be used for future research of many diseases or conditions. If the research investigator distributes your information to other researchers or institutions, your information will be labeled with a research code without identifiers so that you cannot be identified. No additional consent will be requested for the future use of your information.

Are there costs associated with this research? Will I receive any payments?

There will not be any costs associated with participating in this research. The costs of your clinical care will be covered by your health insurer.

You will be paid for completion of each study follow-up visit that you complete. This will add up to between \$40 and \$110 depending on the number of research activities that you complete. If you leave the research early, or if we have to take you out of the research, you will be paid only for the visits you have completed.

You will be issued a ClinCard, which is a specially designed debit card for clinical research onto which your funds will be loaded as appropriate. When a study visit is completed, funds will be loaded onto your card. The funds will be available within 3 days and can be used as you wish.

If I do not want to take part in this research, what are the other choices?

If you do not join this research your doctor will continue to treat you for Lyme meningitis.

**Are there other things I should know about?**

If we find out about new information from this research or other research that may affect your health, safety or willingness to stay in this research we will let you know as soon as possible.

Why would I be taken off the study early?

The research investigator or N.I.A.I.D. may take you out of this study at any time. This would happen if:

- The research is stopped.
- You are not able to attend the research visits required
- The treatment team feels that it is in your best interest to be taken out of this research. If this happens, the research investigator will tell you.

Other information that may help you:

Boston Children's Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research. If you have questions or concerns, you may email IRB@childrens.harvard.edu or call (###) ###-#### between the hours of 8:30 and 5:00, Monday through Friday.

Who may see, use or share your health information?

A copy of this consent form will not be placed in your medical record. The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.

Identifiable study data and for some participants facial photography will be securely sent and stored by the study data coordinating center located at the University of Utah (Salt Lake, UT). Photos will be reviewed by a neurologist who is a consultant to the University of Utah. Study team members at Boston Children's Hospital (Boston, MA) will provide reminders when needed to complete electronic surveys. Qualitative interviews will be completed and analyzed by a team at Rhode Island Hospital (Providence, RI).

Contact for Future Studies:

Your participation in any research is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.

Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

- _____ Yes, I may be contacted about participating in other research projects studying Lyme disease or related conditions. I give permission for my contact information



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(name and mailing address and/or phone number) to be given to other researchers working with the study investigator at Boston Children's Hospital.

No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies.

What should you know about HIPAA and confidentiality?

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study;
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it;
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital;
- People at Boston Children's Hospital who oversee, advise and evaluate research and care. This includes the ethics board and quality improvement program;
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information, such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
- Sponsors or others who fund the research, including the government or private sponsors.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories and others;
- People or groups that are hired to conduct and analyze qualitative interviews at Rhode Island Hospital using video-conferencing and remote data collection.
- Your health insurer, for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information.

Other laws may or may not protect sharing of private health information. If you have a question



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about this, you may contact the Boston Children's Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done. We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes.

Your privacy rights

If you want to participate in this research study, you must sign this form. If you do not sign this form, it will not affect your care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however, you cannot get back information that was already shared with others or included in research analysis. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, please contact the research team.

You may have the right to find out if information collected for this study was shared with others for research, treatment or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital's Privacy Officer at (###) ###-####.

Certificate of Confidentiality

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information

**Boston Children's Hospital****RESEARCH CONSENT FORM****Contact Information**

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

<input type="checkbox"/> I can call...	<input type="checkbox"/> At	<input checked="" type="checkbox"/> If I have questions or concerns about
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Investigator:	Phone: (###) ###-####	<ul style="list-style-type: none"> ▪ General questions about the study ▪ Research-related injuries or emergencies
Lise Nigrovic, MD MPH	Pager: (###) ###-#### [###]	<ul style="list-style-type: none"> ▪ Any research-related concerns or complaints
Research Contact	Phone: (###) ###-#### Pager: (###) ###-####	<ul style="list-style-type: none"> ▪ Rights of a research participant ▪ Use of protected health information. ▪ Compensation in event of research-related injury
Institutional Review Board	Phone: (###) ###-####	<ul style="list-style-type: none"> ▪ Any research-related concerns or complaints. ▪ If investigator/research contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Research Contact or research staff.
<ul style="list-style-type: none"> ▪ General questions about the research ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints 		

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.

I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).



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Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

- _____
Date (MM/DD/YEAR) Signature of **Parent #1 or Legal Guardian** Relationship to child

Child Assent

- _____
Date (MM/DD/YEAR) Signature of **Child/Adolescent Participant**
- If child/adolescent's assent is **not** documented above, please indicate reason below (check one):
- Assent is documented on a separate IRB-approved assent form
- Child is too young
- Other reason (e.g., sedated), please specify: _____

Adult Participant (if applicable)

- _____
Date (MM/DD/YEAR) Signature of **Adult Participant (18+ years)**

Research Investigator /or Associate's Statement & Signature
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- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits. I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital's privacy notification (if requested).

- _____ Date (MM/DD/YEAR)
Signature of **Research Investigator or Associate**



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Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

- The individual cannot read and this consent document was read to the participant or legal **or** representative,
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The individual has certain communication impairments that limit the participant's ability to clearly express consent

I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

- _____
Date (MM/DD/YEAR) Signature of Witness

Or

- The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

- _____
Date (MM/DD/YEAR) Signature of Witness

**Boston Children's Hospital****RESEARCH ASSENT FORM**

Protocol Title: Comparative effectiveness and complications of intravenous ceftriaxone compared with oral doxycycline in Lyme meningitis

Principal Investigator: Lise Nigrovic, MD MPH

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about the treatment for Lyme meningitis. You are being asked to join the study because you have been diagnosed with Lyme meningitis.

If you agree to join this study, your treatment will be the exact same as if you were not in the study. Your doctors will still work with your family to choose the treatment they believe is best for you. We seek to find out how well this treatment works by asking you to report how you are feeling every day (up to 30 days) until you get better. If your face is not moving normally due to the Lyme disease, we will ask you to provide weekly pictures showing how your face moves. At 6 weeks, we may ask you and your parent questions about how you are feeling and your thoughts about the treatment you received.

The risk of study participation is possible disclosure of your confidential medical information. We will do everything possible to prevent that from happening

Being in this study will not help you, but we hope that what we learn will help other people with Lyme meningitis someday.

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study now and change your mind later.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study please feel free to contact the Pedi Lyme Net study coordinator [###-###-### or by page at ###-###-#####].

If you sign your name below, it means that you agree to take part in this research study.

Child/Adolescent Assent_____
Date (MM/DD/YEAR)_____
Signature of **Child/Adolescent Subject**