

**LIAM'S LAND ORGANIZATION, INC.
LYMPHATIC MALFORMATION REGISTRY**

Welcome to the LLO Lymphatic Malformation Registry!

Lymphatic malformations (old term - cystic hygromas or lymphangioma) are rare benign cysts found in 1 in 4,000 births. The lymphatic malformations are channels of abnormal development of the lymphatic system. Majority of LM's are found at birth or before 2 years of age. LM's are frequently found in the neck, floor of mouth, and tongue, but can also be found in other areas of the body.

The LM Registry was established in 2011 by Liam's Land Organization, Inc., a non-profit 501c3, whose mission is to advance research and identify possible cause of the lymphatic malformations while tracking patients and outcomes.

The goal of the LM Registry is to collect and aggregate information regarding the medical history of the parents before and during pregnancy with children and adult individuals affected by lymphatic malformations. The LM Registry will acquire information on the exposures to medication, diet, and environment. It will also track the treatments and the outcomes in order to establish standard protocols and have a better understanding regarding best practice. It is only through obtaining this information that we can hope to stimulate further research interest and encourage the development of new clinical trials that will benefit those individuals affected by lymphatic malformations. Genetic research is in its early stage. This registry will only aid scientist and physicians in the LM research field.

The LM Registry is a confidential database that contains information about individuals and parents of children with the diagnosis of lymphatic malformation. This comprehensive registry will function as a repository of data that will aid the future ability of health care professionals to accurately identify, categorize, treat and possibly prevent this challenging disease.

The LM Registry operates under the guidance and direction of LLO's Executive Officers and Board of Directors. The LM Registry results will be reviewed with LLO's Medical Advisory Board annually in association to the LLO Medical Grant deliberations.

In addition, it is extremely important to this project that we are able to obtain accurate information from you. We strongly encourage you to speak to your physician(s) if you have any questions of uncertainty regarding medical history you are providing.

Please understand that while this process may be time-consuming on your part, it is extremely necessary to try to fully complete the questionnaire. Consents will be required in order to protect both the confidentiality and integrity of this database. We thank you in advance for your patience and appreciate your time commitment to complete this important registry.

Janet E. Steffen, R.N.
Founder/Executive Director

Research Consent

Thank you for the consent to participate and filling out this questionnaire. It is very important that you answer every question. If you do not know the answers to a medical question, please try to contact your doctor(s) to see if he or she knows. Relatives can answer historical information. If you cannot acquire the information, please leave the question unanswered. If your child has lymphatic malformation, you are being asked to complete a questionnaire about you and your partner's medical history along with exposures before and during pregnancy. If you are the individual with a lymphatic malformation or adopted, we ask that you get information from your parents or adoption agencies, if applicable. If your parents are uncertain, please see if their healthcare professional can help. It is vital the database is completed to the best of your ability.

The purpose of this study:

1. To gather medical history of parents before and during pregnancy with children affected by lymphatic malformation and to acquire information on the exposures to medication, diet, and environment and possibly gain an etiology.
2. To track the prevalence and incidence of lymphatic malformations.
3. To supply researchers/clinical trials patient information only with the consent of the patient/legal guardian.
4. To track the outcomes of treatments and procedures.
5. To establish protocols and best practice.

The database will study: basic medical history of parent; symptoms during pregnancy; incidence and frequency of over-the-counter and prescription medications, and diet; the exposures to environmental factors at home, work, or other; exposure to bacterial or viral infections during pregnancy; participation of seasonal vaccines; extent and location of the disease; treatment/surgery used. Through this study we hope to identify patterns of frequency associated with lymphatic malformations and continue to track outcomes.

Your LM Registry information will be assigned a personal and confidential code which will be given to you. When your completed registry arrives at LLO's office, your personal information (name, address, phone number, email, etc) will be separated from the information you supply about your medical and pregnancy history. The staff will input your information into the database using your assigned code number. Researchers who use the information will not have access to your personal information without your consent. Only LLO Registry staff or affiliated non-profit healthcare institution will have access to confidential personal information. Results will be compiled so that they can be analyzed anonymously. If researchers indicate that they need more information, or would like to initiate a sub-study, only LLO's staff or affiliated non-profit healthcare institution will be in contact with participants individually with your consent. There are some risk and benefits to this LM Registry. It will take time to complete the questions. You could be sent additional questions only if we have your consent initialed below. There is a loss risk of confidentiality of the information that you provide. We have taken appropriate measures (see confidentiality above and below) to ensure that your information remains confidential.

I give the Liam's Land Organization Registry staff and/or affiliated non-profit healthcare institution permission to contact me if further information or data is needed.

_____ (initials) _____ (date)

If during the course of this study, there are new findings related to lymphatic malformations or you may be eligible for a clinical trial, you will be notified only if we have your consent.

I give the Liam’s Land Organization Registry staff and/or affiliated non-profit healthcare institution permission to contact me if there are new findings or clinical trials related to lymphatic malformations. _____ (initials) _____ (date)

PARTICIPANT’S STATEMENT

- I understand that I can voluntarily enter and/or withdraw from this project without loss of benefits or information to which I might otherwise be entitled.
- I understand that the LLO and affiliated non-profit institution supplies no institutional benefit or financial compensation from this registry.
- I understand that my name will not be used in any publication resulting from the research.
- I understand that all records relative to the research will be treated in confidence, being available only to the staff of LLO, researchers, and affiliated non-profit healthcare institution.
- I understand that if I have any questions relating to this project that I am free to contact LLO at info@liamsland.org
- I (my child) have (has) voluntarily agreed to participate in this research project. I understand the purpose of the project and the risks/benefits involved in participation.

Date <input type="checkbox"/>	I agree to the terms above Signature _____
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HIPAA Consent

It is the obligation of the LLO and affiliated non-profit healthcare institution to protect the confidentiality of this registry. Information contained in the registry is confidential and protected by Federal and State law. All records are the property of LLO and affiliated non-profit healthcare institution and shall not be removed without the permission of the Executive Director, or her/his designee. This policy applies to all members of the foundation’s workforce including but not limited to employees, contractors, medical staff, volunteers, physician office staff, and other persons releasing protected health information pursuant to a request.

Please read the following informative statements before you sign your consent:

- LM Registry data will be captured using a personal and confidential code.
- The transmission and transfer of the registry data will be protected by a Secure Sockets Layer (SSL) security model.
- Registry data will be stored on a secure database server in a datacenter with controlled facility access.
- Workforce data authorization to registry data will be managed by LLO officials and affiliated non-profit healthcare institution.
- In the event of a records breached, you will be notified immediately of the incident.
- Please retain an additional copy of this form for your records.

Date <input type="checkbox"/>	I give LLO and/or affiliated non-profit healthcare institution my permission for the following information to be entered into a Secure Socket Layer (SSL) security model and understand that the information will be used for research only and all information confidential. Signature _____
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Registry Consent

The purpose of the LM Registry is to study of causes/etiology related to lymphatic malformations. The LM Registry will be able to track outcomes with future participation requested annually with consent of patient/legal guardian. The LM Registry will also be able to locate appropriate patients for clinical trials only with the consent of patient/legal guardian.

Please read the following informative statements before you sign your consent:

- The data you provide may be used in scientific publications, in summary form only as aggregated data with all personal information removed.
- Your name will not be released to any individuals outside of the foundation or researchers without your written consent, nor will it be sold for advertising or fund raising.
- Participation in the LM Registry does not come with a cost to you and entirely voluntary.

<input type="checkbox"/> Date	I give LLO and/or affiliated non-profit healthcare institution my permission for the following information to be entered into LM Registry and understand that the information will be used for research only and all information confidential. Signature _____
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<input type="checkbox"/> Date	I give LLO and/or affiliated non-profit healthcare institution my permission to be contacted annually for an update on treatments/surgeries and progress and understand that the information will be used for research only and all information confidential. Signature _____
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Creating Account

Please fill out the following required fields to create a User in the registry. *Please PRINT clear and in English.*

Participant First Name	
Participant Last Name	
Street Address	
City	
State	
Zip	
Relationship to LM	
Email address	
Confirm email address	

LM First Name	
LM Last Name	
Date of Birth	
Birth City	
Birth State	
Birth Country	

How did you find out about this registry? Website Flyer/Brochure Facebook
 Another LM family Yahoo Support Group

If LM family, who? _____

For LLO office only: Code will be mailed to patient/legal guardian. Please retain for your records when you receive.

Confidential Code	<input type="text"/>
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For LLO office only:

Confidential Code	
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Lymphatic Malformation Database

Objective: To collect a broad history from parents/patients dealing with lymphatic malformation allowing data to be aggregated for possible link to understanding etiology of the disease and track the incidence of this disease and to track outcomes in order for best practice to be established.

LM History – Part I

1. Below information is BEFORE any treatments or surgeries:

	% Microcystic	% Macrocystic
LM %		

LM Location	<input checked="" type="checkbox"/>	Circle appropriate items
Cervicofacial		Stage : I II III IV V
		Macroglossia: Yes No
Axillary		
Abdomen		
Arm		
Lungs		
Other		Location:

2. Other diagnosis's: _____

3. List all treatments/surgeries to date starting from the first treatment/surgery. Include drug used for each sclerotherapy. Include type of laser, if known. *If more room is needed, please attach information on a separate page to back of registry):*

Trach:	Yes	No	Not now
G-tube:	Yes	No	Not now

Date	Surgery/Treatment Name	Result (excellent, good, fair, poor)
Date (continued)	Surgery/Treatment Name	Results (Excellent, good, fair, poor)

For LLO office only:

Confidential Code	<input type="text"/>
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OBSTETRICAL HISTORY – Part II

Age of mother at time of LM pregnancy	
Blood type of mother	
Blood type of LM individual	
Have you ever received RhoGAM? Y N	
<i>If yes, date(s) and lot #(s), if available:</i>	

Age of father at time of LM pregnancy	
Blood type of Father	

Please list number of:

Pregnancies		Miscarriages		Premature Births	
Abortions		Live births		Living children	
Stillbirths					

No.	Birth Date	Birth Weight	Male/Female (circle)		Week of Pregnancy	Type of delivery (circle)		Complications
			M	F		Vag	C/S	
1.			M	F		Vag	C/S	
2.			M	F		Vag	C/S	
3.			M	F		Vag	C/S	
4.			M	F		Vag	C/S	
5.			M	F		Vag	C/S	
6.			M	F		Vag	C/S	
7.			M	F		Vag	C/S	

When did you find out you or your child had lymphatic malformation?						
1 st trimester	2 nd trimesters	3 rd trimester	0-1 yo	1-3 yo	> 4yo	
Level I prenatal ultrasound with blood work (during 1 st trimester)?						Y N
CVS testing?						Y N
Level II prenatal ultrasound with blood work (during 2 nd trimester)?						Y N
Normal genetic testing?						Y N
<i>If no, please give the name of genetic disorder:</i>						
Access to prenatal care?						Y N
<i>If yes, weeks of pregnancy on 1st exam:</i>						
Did you take a prescription prenatal vitamin?						Y N
Did you take over the counter prenatal vitamin?						Y N
Did you take H1N1 in 2009/2010?						Y N
<i>If yes, approximate number of gestational weeks:</i>						

Did you take the seasonal flu shot?	Y	N
<i>If yes, approximate number of gestational weeks:</i>		
Did you use an electric blanket or become overheated during your pregnancy?	Y	N

Please list any over-the-counter and prescription medications taken during your pregnancy only by the mother: *(Please include even if taken one time.)*

Medication Name / Dosage	Approx. start date	Gestational Weeks	Approx. end Date	Gestational Weeks	Reason

Please list any over-the-counter and prescription medications taken during your pregnancy only by the father during the time of trying to conceive through conception: *(Please include even if taken one time.)*

Medication Name / Dosage	Approx. start date	Gestational Weeks	Approx. end Date	Gestational Weeks	Reason

For LLO office only:

Confidential Code	<input type="text"/>
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GENETIC HISTORY – Part III

Genetic Disorder	Yes	No	Relationship	Mother's Side	Father's Side
Thalassemia	Y	N			
Neural Tube Defect (meningomyelocele, spina bifida,	Y	N			

anencephaly)					
Congenital Heart Disease	Y	N			
Down Syndrome	Y	N			
Tay-Sachs (Jewish, French Canadian)	Y	N			
Canavan Disease	Y	N			
Sickle Cell Disease or Trait	Y	N			
Hemophilia or other blood disorders	Y	N			
Muscular Dystrophy	Y	N			
Cystic Fibrosis	Y	N			
Huntington's Chorea	Y	N			
Mental Retardation/Autism	Y	N			
<i>* If yes, was person tested for Fragile X?</i>			<i>Y</i>	<i>N</i>	
Other inherited genetic or Chromosomal Disorder	Y	N			
<i>*If yes, what _____</i>					
Genetic Disorder	Yes	No	Relationship	Mother's Side	Father's Side
Maternal metabolic disorder *(DM, PKU, Etc)	Y	N			
Do you or the baby's father have a child with a birth defect not listed above?	Y	N			
<i>*If yes, mother/father and what _____</i>					
Do you or the baby's father have a birth defect?					
<i>If yes, mother/father and what _____</i>					

For LLO office only:

Confidential Code	<input type="text"/>
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HOME/INFECTION/WORKPALC/ENVIRONMENT HISTORY– Part III

Year of home which LM child/patient lived during gestation?	
Exposed to lead paint?	

<i>If no, do you have a "lead free" certificate if applicable?</i>							
Type of utilities?				Gas	Electric	Both	
Water supply?				City	Well		
Pets in home?							
	Breed	Long Hair	Short Hair	Sheds	Indoor	Outdoor	In/Outdoor
Dog (s)							
Cat (s)							
Other							
Exposed to chemicals (paints, pesticides, fumes, etc)?				Y	N		
<i>If yes, what chemicals?</i>							
Exposed to radiation?				Y	N		
<i>If yes, why?</i>							
Exposed to chemotherapy?				Y	N		
<i>If yes, name of chemotherapy(s)</i>							
Used tanning bed at any time during your pregnancy?				Y	N		
<i>If yes, early, late, entire pregnancy?</i>							
Exposed to infections in work environment (hospitals, lab work, day care, teaching, etc)?				Y	N		
<i>If yes, what kind(s)?</i>							
Rash or viral illness during pregnancy?				Y	N		
Use of hair dyes or medicated shampoo?				Y	N		
Use of topical creams/ointments				Y	N		
<i>If yes, names?</i>							

For LLO office only:

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SOCIAL HISTORY – Part IV

Drug	1 st trimester/ Amount/frequency		2 nd trimester/ Amount/frequency		3 rd trimester/ Amount/frequency	
	Y	N	Y	N	Y	N
Tobacco	Amount:		Amount:		Amount:	
	Frequency:		Frequency:		Frequency:	
	Caffeine	Amount:		Amount:		Amount:
Frequency:		Frequency:		Frequency:		
Alcohol		Amount:		Amount:		Amount:
	Frequency:		Frequency:		Frequency:	
	Street/Recreational Drug Type(s)_____	Amount:		Amount:		Amount:
Frequency:		Frequency:		Frequency:		

Was your pregnancy stressful? Yes No

On a scale of 1 to 10 (with 1 being stress free and 10 being the most stressful, what number would you rank your stress level during pregnancy? _____

For LLO office only:

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DIET HISTORY – Part VI

Food	1 st trimester/ Amount/frequency		2 nd trimester/ Amount/frequency		3 rd trimester/ Amount/frequency	
	Y	N	Y	N	Y	N
Raw or partially cooked eggs	Amount:		Amount:		Amount:	
	Frequency:		Frequency:		Frequency:	
	Soft cheeses	Amount:		Amount:		Amount:
Frequency:		Frequency:		Frequency:		
Unwashed veggies or fruits		Amount:		Amount:		Amount:
	Frequency:		Frequency:		Frequency:	
	Fish with	Amount:		Amount:		Amount:
Frequency:		Frequency:		Frequency:		

mercury (Swordfish, King Mackerel, Tuna, etc)	Amount:	Amount:	Amount:
	Frequency:	Frequency:	Frequency:
Smoked Seafood	Y N	Y N	Y N
	Amount:	Amount:	Amount:
	Frequency:	Frequency:	Frequency:
Raw seafood/Sushi	Y N	Y N	Y N
	Amount:	Amount:	Amount:
	Frequency:	Frequency:	Frequency:
Deli Meats	Y N	Y N	Y N
	Amount:	Amount:	Amount:
	Frequency:	Frequency:	Frequency:
Artificial Sweeteners	Y N	Y N	Y N
	Amount:	Amount:	Amount:
	Frequency:	Frequency:	Frequency:

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