



# LIMB LOSS and PRESERVATION REGISTRY

Activity is health.

## What's in the LLPR Participation Agreement?

*Purpose: To provide prospective registry participants a summary of the key elements of the registry agreement to enhance their understanding to allow them to more quickly identify potential questions they may have.*

### LLPR PARTICIPATION AGREEMENT

9 pages, execution required

<b>PARTIES</b>	Mayo Clinic ("Mayo") and O&P Provider ("Participant")
<b>TERM</b>	One year from date of execution with auto one-year renewals, unless written notice of termination at least 30 days prior to anniversary of effective date.
<b>WHEREAS</b>	1. Mayo and National Institute of Health ("NIH") have contracted to develop and operate LLPR. 2. Participant desires to participate in LLPR and Mayo desires to receive data from Participant.
<b>CONSIDERATION</b>	Exchange of data through web-based portal to result in reports. LLPR requirements include compliance, record management, privacy, and information security.
<b>COST</b>	Initial participation is without charge. Subscription fees may be charged in the future with 60 days advance written notice.
<b>CONFIDENTIALITY</b>	Both parties will take all reasonable and professional steps to maintain confidentiality of protected health information ("PHI") and electronic protected health information ("EPHI") under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH") regulations.
<b>DATA OWNERSHIP</b>	Remains with Participant. Provided to Mayo to fulfill NIH Contract for LLPR.
<b>LIABILITY</b>	Neither party liable to the other for any specified damages.
<b>LIMITATION OF LIABILITY</b>	Each party to agreement is responsible for own acts and omissions.
<b>DISCLAIMER OF WARRANTY</b>	All reports provided by Mayo are "as-is", disclaimers provided.
<b>INSURANCE</b>	Each party shall maintain general and professional liability insurance.
<b>BOILERPLATE CONTRACT TERMS</b>	Include equitable relief, independent contractors, notice requirements, assignment, waiver, choice of law, severability, survival, access to records, etc.

(continued on next page)

## APPENDIX I, NIH CONTRACT – CERTIFICATE OF CONFIDENTIALTY (“CoC”)

*2 pages, no execution required*

Mayo, as Contractor with NIH, “shall protect the privacy of the individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act as a term and condition of contract.”

The CoC defines the research, provides permitted disclosures, and requires Contractor maintain effective internal controls that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

## APPENDIX II, BUSINESS ASSOCIATE AGREEMENT (“BAA”)

*9 pages, execution required*

### PARTIES

Mayo Clinic (“Mayo”) and O&P Provider (“Participant”)

### WHEREAS

BAA is connected to LLPR Participation Agreement and sets forth desire to submit and receive PHI, and comply with all applicable requirements of HIPAA and HITECH.

### CONSIDERATION

Exchange of mutual promises, conditions and other good and valuable considerations, parties agree to do business as described in following sections:

- 1.DEFINITIONS;
- 2.APPLICABILITY OF TERMS;
- 3.BUSINESS ASSOCIATE OBLIGATIONS;
- 4.PERMITTED USE AND DISCLOSURES BY MAYO;
- 5.BUSINESS ASSOCIATE REPORTING OBLIGATIONS;
- 6.GENERAL OBLIGATIONS OF PARTICIPANT;
- 7.TERM AND TERMINATION;
- 8.INDEMNIFICATION;
- 9.MISCELLANEOUS.

*For more information on the Participation Agreement and/or to schedule a call with the LLPR team to learn more about the registry, please email us at [info@llpregistry.org](mailto:info@llpregistry.org).*



@llpregistry



<https://www.linkedin.com/company/llpregistry/>



**The LLPR is the first national database of its kind which collects limb loss and limb preservation patient data and performs insightful analyses.**

The project is a sole source contract to Mayo Clinic funded in whole or part with Federal funds from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services with the Department of Defense, under Contract No. HHSN275201800005I.