

THE FERASAFE® REGISTRY PARTICIPATION AGREEMENT

THIS AGREEMENT is entered into and made effective the ____ day of _____, 2016 ("Effective Date"), by and between (a) the Regents of The University of California, on behalf of its Los Angeles campus ("UCLA") and b)

_____,
"Contributing Institution"), on behalf of _____ ("Contributing Investigator").

WHEREAS, UCLA owns and manages the FeraSafe® Registry (the "Registry") consisting of certain computerized databases containing information relating to patient treatment, the practice of medicine, and third party patient data submitted to these databases pursuant to rules developed UCLA and the FeraSafe® Registry steering committee (the "Steering Committee"); and

WHEREAS, Contributing Investigator has expressed an interest in contributing to the Registry in accordance with this Agreement and Steering Committee requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants contained herein, and for other good and valuable consideration, the parties hereto agree as follows:

1. Participation in the FeraSafe® Registry.

1.1 Contributing Investigator will participate in the data collection conducted by the Registry by contributing de-identified safety data and /or de-identified image data ("Data") to the Registry through the web-based portal, and otherwise complying with the rules and collection schedules reasonably established by Steering Committee in connection therewith.

1.1.1 Contributing Institution hereby represents and warrants on behalf of the Contributing Investigator that to the best of its knowledge, all Data submitted for inclusion in the Registry will be accurate, complete, and will not infringe on any third party's rights. Contributing investigators will use reasonable efforts to address any Data or related deficiencies identified by the Steering Committee. Upon request from the Steering Committee, Contributing Investigator agree to provide the Data at reasonable periods. Contributing Investigators agree to inform the Steering Committee with any change to its Data format.

1.1.2 Contributing Investigators further promise to take all reasonable steps to avoid the submission of duplicative Data for inclusion in the Registry, and agree to assist and cooperate with the Steering Committee in its efforts to conduct the Registry.

1.1.3 Contributing Institution shall be responsible for and agrees to indemnify UCLA for the negligent acts and omissions of its employees and agents, including Contributing Investigator, in submitting Data to the Registry.

1.1.4. Contributing Institution understands that the Steering Committee provides the Registry “as is” and makes no warranties regarding the Registry, either express or implied, including no warranty of merchantability or fitness for a particular purpose.

1.2 Contributing Institution represents and warrants that the Data they submit to the Registry will be de-identified and shall not include protected health information (“PHI”). Contributing Institution represents and warrants that it has obtained all applicable permissions or waivers from its institutional review board (“IRB”) or other relevant regulators, which may be required in order to submit such Data for inclusion in the Registry.

2. Ad Hoc Queries by Contributing investigators. Contributing Investigator may submit requests for ad hoc queries (requiring access to and analysis of aggregate Data from the Registry) to the Steering Committee for analysis. All such requests for ad hoc queries shall be subject to prior approval by the Steering Committee, in accordance with such procedures and other requirements as it may reasonably establish, before efforts are undertaken to respond thereto. In its response to each of Contributing Investigator’s ad hoc queries, the Steering Committee shall give due consideration to scientific merit, the funds and other resources available to address ad hoc queries, qualifications of the Contributing Investigator to address the specific scientific question, and other pertinent factors.

3. Registry Funding. Contributing Investigator acknowledges that the Steering Committee may from time to time seek sponsorships or other forms of commercial funding to help sustain the Registry for research purposes. Contributing Investigator agrees that such funding opportunities may include allowing access to de-identified Registry Data submitted by all Contributing Investigators for research purposes.

4. Intellectual Property; Benefits to Contributing investigators.

4.1 It is agreed and acknowledged that all local Data submitted for inclusion in the Registry by Contributing Institution or on behalf of Contributing Investigators are and shall remain proprietary information belonging to the Contributing Institution. The Contributing Institution hereby grants to UCLA a perpetual royalty-free license to use and allow Registry sponsors, the Steering Committee and other third party researchers approved by the Steering Committee to use the Data for research purposes.

4.2. Contributing Institution on behalf of Contributing Investigator will receive the following benefits from submitting Data to the Registry:

4.2.1 Each Contributing Investigator will be informed in writing by the

Steering Committee of any research project that will involve usage of Contributing Investigator's data and that has been approved by the Steering Committee.

4.2.2 Such notified Contributing Investigator will then have the option to participate in the research project that has been proposed, which includes the data from the Contributing Investigator's site. Terms will be mutually agreeable to both the investigator requesting data ("Requesting Investigator") and Contributing Institution. Recognition and/or authorship by the Contributing Investigator will be considered by the Steering Committee based on scientific merit, other potential co-authors, time and effort provided to the research, and available funding to support the project. Other factors may also be required in the decision-making process as deemed appropriate by the Steering Committee.

4.3 Contributing Institution acknowledges that UCLA is and shall be deemed the owners of all rights to the Registry (including the aggregate data contained therein and subsets thereof), and all trademarks associated with the Registry (including, without limitation, FeraSafe and all variations thereon and graphic representations thereof), (collectively, "FeraSafe") with the exception of Contributing investigators' Data.

4.4 Neither party shall use the name, trademark, or logo of the other party or its employees for promotional purposes without prior written consent of the other party.

4.5 Contributing Institution agrees that UCLA may identify on its website Contributing Investigator as a Registry participant.

5. Limitation of Liability. Each party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other party and the results thereof. Each party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. Under no circumstances will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

6. Term and Termination.

6.1 Subject to the terms of Section 6.2, this Agreement shall be effective for a period of one (1) year and shall be automatically renewed on an annual basis thereafter unless any party provides the other(s) with a written notice of termination at least 30 days prior to the expiration of any term.

6.2 This Agreement may be terminated upon any party's material breach of this Agreement, provided, however, that if said breach is cured to the non-breaching party's satisfaction within thirty (30) days after the provision of such notice, said

termination notice shall of no further force or effect and this Agreement shall be fully reinstated.

6.3. Upon termination of this Agreement, Contributing Investigator shall have the option of asking that its Data in the Registry be removed at the later of the date of termination or the conclusion of any pending research projects using the Data.

7. Equitable Relief. The parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that each party shall be entitled to seek emergency injunctive relief as a remedy for any such breach by any other party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching party.

8. Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint ventures.

9. Notices. All notices and demands of any kind or nature which any party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, by facsimile transmission, by overnight courier or by electronic mail to the following addressees:

If to Contributing Institution:

Email: _____
Attn: _____

If to UCLA:

Email: _____
Attn: _____

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any party hereto may, from time to time, by notice in writing served upon the other party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

10. Assignment. This Agreement may not be assigned by either party without the prior express written approval of the other party, except that either party may assign this Agreement to an affiliate, successor entity, or subsidiary without the written approval of the other party.

11. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument. Electronic signatures shall have the same effect as originals.

12. Waiver. A waiver by any party to this Agreement of any of its terms or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.

13. Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

14. Entire Agreement. This Agreement is supplemented by data use policies attached and to be found at www.ferasafe.org, which are incorporated herein by reference and subject to change from time to time (“Appendix A: Ferasafe® Registry Data Use Policies and Guidelines”). In the event of a conflict between the Ferasafe Policies and this Agreement, the terms of this Agreement shall prevail. Subject to the foregoing, this Agreement (a) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the party against whom enforcement is sought.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, as of the Effective Date first written above.

The Regents of The University of California

Contributing Investigator

By: _____

By: _____

Name: Karla Zepeda

Name: _____

Title: Associate Director, ISR

Title: _____

Date: _____

Date: _____