



International Nipple SParing mastectomy Registry

INVESTIGATOR'S AGREEMENT

The Investigator has agreed to participate in the conduct of a nipple sparing mastectomy (NSM) registry in compliance with the requirements of the Protocol entitled INSPIRE. This Registry has been designed to compile information on NSM. It is a multi-center, non-randomized, prospective registry. Investigator agrees to use his best efforts and professional expertise to perform the Registry in accordance with the Protocol, applicable state and local laws, rules, regulations and standards and governmental agency requirements, and the terms and conditions of this Agreement.

Each patient who wishes to participate in the Registry will be required to sign a PATIENT PERMISSION to Act as a Participant in the INSPIRE. The Investigator shall be responsible for obtaining such permission from each patient prior to his/her participation in the Registry. Each permission must be signed by the patient AND only data from patients with signed permission will be included in the Registry.

Investigator agrees to provide EURECCA periodically and in a timely manner during the term of this Agreement with the data called for in the Protocol. Investigator agrees to maintain the confidentiality of all patient-related information acquired during the course of the Registry,

Investigator acknowledges and agrees that he or she obtains no right, title or interest in or to any of the data included in the Registry or any other results of the Registry or any work product created in connection with the Registry. Investigator further acknowledges that all patient data regarding patients participating in the Registry and included in the final validated database of the Registry (as described in the Protocol) shall be and remain property of EURECCA.

Investigator agrees that all data, results, documentation and other work products made by him or her, alone or with others, are works made for hire for EURECCA and, therefore, EURECCA shall retain all rights to and ownership in such works for hire. Additionally, Investigator hereby makes and agrees to make all assignments necessary to accomplish the foregoing ownership.

EURECCA representatives may visit Investigator's facility with reasonable frequency and upon reasonable notice, to observe the progress of the Registry. Investigator shall make all Registry-related materials, including case report forms and source documents, available to EURECCA for inspection at reasonable times during normal business hours during the conduct of the Registry

The term of this Agreement shall commence on the date first written above and shall terminate upon completing of the Registry, unless terminated earlier as provided herein. The Agreement shall further termination automatically, without action by either party, upon termination of the Participation Agreement between EURECCA and the Investigator or the entity with which the Investigator is engaged.

This Agreement may not be altered, amended or modified except by written document signed by both parties.

INSPIRE

Name:

Title:

Date:

INVESTIGATOR

Name:

Title:

Date:

Institution