**Glia**
**June 13, 2015**
**London, ON**

# Distribution Record Protocol

## 1.0 Introduction

Glia's **Distribution Record Protocol** is informed by Health Canada's **Medical Device Regulations (SOR/98-282)**[1], and follows the requirements for distribution records outlined in Sections 52-56.

## 2.0 Distribution Record Protocol

As per **Section 52:**

(1) The manufacturer, importer and distributor of a medical device shall each maintain a distribution record in respect of each device.
(2) Subsection (1) does not apply to
    (a) a retailer; or
    (b) a health care facility in respect of a medical device that is distributed for use within that facility.

**Glia is a manufacturer and distributor of medical devices, and thus creates and maintains distribution records of its manufactured medical devices. This includes items that are sold, donated, or given away for the purposes of use, research, and/or demonstration.**

As per **Section 53:**

The distribution record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market.

**As per Health Canada guidelines, in the unlikely event of a recall, Glia's distribution records include detail sufficient to identify the faulty device. Distribution records are entered on a standard distribution form, and include the following information:**

**Name of the device**
**Device identifier**
**Date the device was printed, manufactured, or produced**
**Lot number**
**Number of units shipped or distributed**
**Date of distribution to the recipient**

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[1] Health Canada: Medical Devices Regulations (SOR/98-282). (2011). Retrieved from: http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-12.html#h-40

**Address of the recipient**[2]

As per **Section 54:**

(1) The distribution record maintained by a manufacturer of an implant shall also contain a record of the information received on the implant registration cards forwarded to the manufacturer from a health care facility pursuant to section 67.
(2) The manufacturer of an implant shall update the information referred to in subsection (1) in accordance with any information received from the health care facility or the patient.

**Glia does not produce medical devices that would qualify as an implant. Thus, Glia does not have protocol related to Section 54.**

As per **Section 55**:

The manufacturer, importer and distributor shall retain the distribution record maintained in respect of a medical device for the longer of

(a) the projected useful life of the device, and
(b) two years after the date the device is shipped.

**Glia retains all distribution records for the life of the device, plus one year.**

As per **Section 56:**

Distribution records shall be maintained in a manner that will allow their timely retrieval.

**Glia retains its distribution records in a secure, password protected computer located at 311 Hyman St, London, Ontario.**

**Storing the records in the computer allow for immediate access and retrieval in the event of record review, audit, complaints, or recall.**

**3.0 Document References**

Health Canada: Medical Devices Regulations (SOR/98-282). (2011). Retrieved from: http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-12.html#h-40

Health Canada: Guide to Recall of Medical Devices (GUI-0054). (2011). Retrieved from: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054_recall-retrait-doc-eng.php#sec5256_42

[2] Health Canada: Guide to Recall of Medical Devices (GUI-0054). (2011). Retrieved from: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054_recall-retrait-doc-eng.php#sec5256_42