

HLS THERAPEUTICS INC.

PATIENT PRIVACY POLICY

Definitions

Privacy Officer: The person within HLS Therapeutics ('HLS') who is responsible for ensuring compliance with privacy obligations, including this Policy, with respect to the collection, use, disclosure and handling of personal information by HLS and its authorized agents.

Collection: Refers to the act of gathering, acquiring, recording or obtaining personal information from any source.

Consent: Voluntary agreement to the collection, use and disclosure of personal information for defined purposes. Consent can be express or implied and can be provided directly by the patient or by an authorized representative. Express consent can be given orally, electronically or in writing but is always unequivocal and does not require any inference on the part of HLS. Implied consent can be reasonably inferred from an individual's action or inaction.

Disclosure: The act of making personal information available to others outside HLS.

Patient Information: Personal information about an identifiable patient that is recorded in any form, including personal health information such as a patient's provincial health card number or drug history. Personal information does not include aggregate information that cannot be associated with a specific individual.

Retention: Refers to the act of keeping personal information as long as is necessary to fulfill the stated purposes, or as long as otherwise specified by law.

Use: Refers to the treatment, handling and management of personal information by HLS.

HLS is committed to protecting and securing the patient information entrusted to us in order to meet our regulatory obligations to maintain a clozapine database. We take great care in managing your personal information. Our priority is to comply with regulatory requirements as well as privacy best practices and data protection laws that apply to HLS.

This privacy policy stands as a reflection of HLS's commitment to privacy and is based on the *Canadian Standards Association Model Code for the Protection of Personal Information* (CAN/CSA-Q830-96).

1 . Accountability

HLS is responsible for personal information under its control. Toward that end, it has established internal procedures to comply with this Policy and has designated a Privacy Officer to be accountable for compliance with the following principles.

1.1. Responsibility for ensuring compliance with the provisions inherent in this Policy rests with the Privacy Officer of HLS. The Privacy Officer will delegate responsibilities to one or more employees as needed to oversee the continued protection of patient information.

1.2. HLS shall make known, upon request, the Privacy Officer and the person or persons designated to oversee HLS's compliance with this Policy.

1.3. HLS is responsible for personal information in its possession or control. It shall use contractual or other means to ensure that third party service providers provide a comparable level of protection while information is being processed by them.

2. Identifying Purposes for Collection of Personal Information

HLS identifies the purposes for which personal information is collected at or before the time the information is collected.

2.1. HLS only collects patient information for the following purposes:

- a) to maintain accurate data regarding patients' hematological testing and monitoring, side effects, adverse events, and clozapine usage history for the patient's safety and well-being;
- b) to provide hematological results to approved suppliers of clozapine through the CSAN[®] distribution system as needed;
- c) to report statistical (de-identified) data to Health Canada regarding usage of clozapine in Canada; and
- d) to meet other legal and regulatory requirements that are imposed upon HLS from time to time.

2.2. Upon request, the HLS Privacy Officer will further elaborate on these purposes or refer the requesting individual to a designated person within HLS who shall explain the purposes.

2.4. Unless required by law or regulation, HLS shall not use or disclose personal information that has been collected for any new purpose without first identifying and documenting the new purpose and obtaining patient consent.

3. Obtaining Consent for Collection, Use or Disclosure of Personal Information

Knowledge and consent is required for the collection, use or disclosure of personal information, except where inappropriate.

3.1. HLS relies on the patient's treating physician/pharmacist to obtain consent for the entry of patient information into the CLOZARIL[®] registry, and for the sharing of hematological and related data between clozapine providers to ensure patient safety.

3.2. The continued use of CLOZARIL[®] by a patient constitutes implied consent for HLS to continue collecting, using and disclosing patient information for the purposes outlined in Principle 2.1, unless consent has been specifically withdrawn.

3.4. The patient's consent is a condition for the continued supply of CLOZARIL[®]. If a patient or the patient's legal representative withdraws consent at any time, HLS relies on the physician or pharmacist prescribing or supplying the drug respectively, to notify the patient of the consequences of withdrawal and discontinuing the use of clozapine.

4. Limiting Collection, Use and Disclosure of Personal Information

HLS limits the collection, use and disclosure of personal information to that which is necessary for purposes identified by HLS.

4.1. HLS only collects the patient information that is necessary for the purposes identified in section 2.1. This includes the patient's initials, date of birth, provincial health card number and race. HLS also collects the patient's clozapine drug history such as the drug start date, dosage, and reasons for treatment discontinuation if applicable.

4.2. Each patient is assigned a unique CSAN[®] number that is used by approved clozapine suppliers to identify the patient.

4.3. HLS collects patient information indirectly from the patient's treating physician or pharmacist when they fax in the CSAN[®] Form 1, as well as hematological testing results, for secure entry by HLS Clinical Coordinators into the CLOZARIL[®] registry.

4.4. Patient information may be transferred to a foreign jurisdiction to be processed or stored. Such information may be provided to law enforcement or national security authorities of that jurisdiction upon request, in order to comply with foreign laws.

4.5. HLS may also be required to disclose patient information to law enforcement or a government/regulatory body in order to assist with an on-going investigation.

4.6. HLS does not and will not sell any patient information to third parties for marketing or any other commercial purposes.

5. Limiting Retention of Personal Information

HLS retains personal information as long as necessary for the fulfillment of identified purposes, or as required by law.

5.1. Patient information must be retained for the life of the patient, to fulfil the identified purposes for which the information was collected, as set out in Section 2.1. Even if the patient discontinues use of clozapine, the patient's history must be retained in the event of a restart.

5.2. If HLS is notified that a patient has deceased, this information is captured in the registry and the status of the patient is changed to discontinued.

6. Accuracy of Personal Information

HLS makes reasonable efforts to keep personal information as accurate, complete and up-to-date as is necessary to fulfil the purposes for which the information is to be used.

6.1. HLS relies upon the patient's treating physician and pharmacist to ensure accuracy of the information entered on the CSAN[®] Form 1.

6.2. Clinical Coordinators use data validation methods to ensure up-to-date and accurate information is entered into the CLOZARIL[®] registry.

6.3. Once data is saved in the registry, any inaccuracies identified can only be corrected by submitting a new CSAN[®] Form 1.

7. Security Safeguards

HLS protects personal information with security safeguards appropriate to the sensitivity of the information.

7.1. With the use of appropriate physical, administrative and technical security measures, HLS protects patient information against a variety of risks, such as, loss, theft, unauthorized access, disclosure, copying, use, modification or destruction of such information.

7.2. Access to the CLOZARIL[®] registry is limited to HLS employees who require access in order to perform their work duties.

7.3. HLS takes steps to ensure the protection of patient information shared with third parties that are appropriate based on the sensitivity of the information, including the following:

- a) Secure transmission and storage of patient data through the use of tokenization and encryption;

- b) The use of a secure server in a secure data centre for the storage of the CLOZARIL[®] registry;
- c) A strong password policy for access to the registry by health care practitioners; and
- d) Contracts with third parties that stipulate responsibilities to protect personal information and only use it for specific purposes.

8. Openness Concerning Policies and Practices

HLS makes readily available specific information about its personal information management practices upon request.

8.1. This information includes:

- a) The name, title and address of the Privacy Officer to whom inquiries or complaints can be forwarded; and
- b) A description of the type of patient information held by HLS, including a general account of its use and disclosure.

8.2. HLS may refer a patient to their treating physician or pharmacist if they are inquiring about practices that are not under HLS's control.

9. Access to One's Own Personal Information

HLS informs individuals of the existence of his or her personal information upon request, and how to obtain access to such information.

9.1. Patients who want access to their own information in the CLOZARIL[®] registry, or to the source of such information, must submit a request to their treating physician.

9.2. Access to personal health information will be provided in accordance with the provisions of applicable data protection laws.

10. Challenging Compliance

An individual shall address a challenge concerning HLS's compliance with the principles set out in this Policy to the Privacy Officer.

10.1. Any inquiries by individuals with regards to HLS's handling of patient information shall be promptly addressed.

10.2. Any complaints concerning compliance with this Policy shall be investigated by HLS. If a complaint is found to be justified, HLS shall take appropriate measures to resolve the complaint including, if necessary, amending its policies and practices.

For more information please contact:

Privacy Officer
HLS Therapeutics Inc.
10 Carlson Court, Suite 410
Etobicoke, Ontario
M9W 6L2
Phone #: 1-647-495-9000
E-mail: privacy@hlstherapeutics.com

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