**SKiD Privacy Notice - Data Protection and Confidentiality Version 23/5/21**

**What is the SKiD database?**

The SKiD database is the UK registry collecting technical and outcome data on those treated with the Sphinkeeper anal bulking procedure for predominantly passive faecal incontinence and who have a defined pattern of anal sphincter injury. The information in the database will be used to confirm the safety of the procedure and assess its efficacy both in terms of symptom severity and quality of life.

**What information does it contain?**

The Skid data base will contain pre-operative clinical and assessment details, operative and technical detail and then regular follow up data on outcome thereafter and at predetermined times. Symptom severity can be provided remotely by the patient to facilitate population of the database. Patients will be seen at regular intervals following the operation for ultrasound assessment. All Sphinkeeper anal bulking operations performed in the UK must be entered on to the registry to maintain compliance with NICE guidelines and the registry will provide a regulatory forum for this service delivery.

**Who manages the SKiD database?**

THD UK Ltd and Dendrite Clinical Systems, our technology partner.

**What happens to the data and who can see it?**

The data are collected by the doctors, nurses, and hospital staff treating and managing the patient. Hospital computers are used to collect the information, which is collated, checked and approved before being sent to a single secure database server on the NHS network. During the data transfer from the hospital to the NHS server the information is encrypted (locked) to ensure it cannot be interfered with. Only an approved member of staff at the hospital can load the data onto the SKiD database. Once the records have been loaded they can be reviewed by authorised staff at the hospital using an approved user account with a secure password.

The information collected is valuable as it allows clinicians to understand the effectiveness of the Sphinkeeper operation over an extended period of time, the profile of patients and the results that are being achieved by hospitals around the country. The data will be analysed by Dendrite Clinical Systems to produce SKiD annual reports. The reports do not contain the details of individual patients. They report results for groups of patients. These are broken down by region or hospital, and by other important information that may be related to outcomes such as age, general health status.

The data will not be shared with any Third Party. It will be used purely to address the efficacy and safety of the Sphinkeeper procedure.

**SKiD Database Server**

The server is hosted on the NHS network (N3) within a data centre in London, by RedCentric. This is a tier three data centre which meets the highest levels of building security.

The service delivery and information governance provided complies with ISO 20000 & ISO 9001 accreditation and the security structure is aligned alongside ISO27001. The security arrangements are internally audited approximately every three months and externally audited every six months.

All servers have firewall and anti-virus software installed which is configured to use real-time scanning.

## Backup Resilience

The data is securely backed-up each day. All backed up data stored is compressed, de-duplicated and encrypted within a secure off-site vault.

There are two backup vaults, the primary one is hosted locally and is then backed up to a secure secondary off-site vault hosted within a separate datacentre located at Heathrow.

**Can I ask to see the data the SKiD registry holds about me?**

Yes - requests to see what data is held on the SKiD database about you may be made through a Subject Access Request via the SKiD welcome page https://hscn.e-dendrite.com/csp/askr/frontpages/index.html

**Can I opt out of the SKiD registry?**

National clinical audit is most effective when it has information from as many patients as possible, and the SKiD Registry collects some specific information to allow us to assess the quality of care delivered to patients. If you do not want this specific information to be used, please tell the people who are treating you. When the people who are treating you inform Dendrite (our technology partner) about your decision, they will make sure that any specific information about you held on the SKiD registry is removed from the audit database and confirm this back to the people who are treating you who will then confirm to you that your data has been removed. This will not affect your treatment in any way.

**Patient Related Outcome Measures (PROMs)**

When you are first seen by the people who are treating you, they will ask you if you are happy to receive emails from the SKiD registry. If you are, emails will be sent to you periodically containing a link which, when you click on it, will present some simple questions related to the treatment that you have received that will enable you to inform the team treating you how you feel.  When you submit those questions, your answers are then submitted into the SKiD registry so that those people treating you can monitor your responses and assess the effectiveness of your treatment.  However, if you choose not to consent to receiving these emails you may do so (and you will not receive these emails) but if you initially consent but then change your mind, please inform the people treating you and they will update the database to ensure you don’t receive any more.

**Dendrite Security**

Dendrite Clinical Systems is assessed against NHS Information Governance standards, which includes both physical and organisational security measures. Dendrite’s toolkit assessment score is available on the IG Toolkit website (https://www.dsptoolkit.nhs.uk/OrganisationSearch/8HJ38).

The computer software program created by Dendrite that holds the SKiD data has been independently tested to ensure that it is not vulnerable to unauthorised access, or internal breaches of security.

**Can I ask to see the data that the SKiD registry holds about me?**

Subject Access Requests to see what data is held on the SKiD database about you may be made through the SKiD Registry Welcome Page https://hscn.e-dendrite.com/csp/askr/frontpages/index.html

**Further information**

Queries should be directed to the SKiD Project team – ig@thdlab.co.uk