**DATA MANAGEMENT PLAN (NOVRET STUDY)**

**Version 1.1**

**October 2021**

**STUDY PROPOSAL**

A randomised, controlled comparative study of the wrinkle reduction benefits of a No-Tox®, a plukenetia/niacinamide/plankton-based topical cosmeceutical formulation vs. 0.5 mg (0.05% w/w) tretinoin, a prescription-strength topical retinoic acid formulation.

*Abbreviated Name: Notox Vs. Retinoid Study (NOVRET Study)*

**Study Location: Skin Surgery Clinic, Auckland**

**Study Coordinator: Dr Sharad Paul, Adjunct Professor Auckland University of Technology; Director, Skin Surgery Clinic**

**Lead/Principal Investigator: Allanah Knight, Nurse Manager, Skin Surgery Clinic**

**This document consists of 4 pages.**

**1. DESCRIPTION OF THE DATA**

**1.1 Type of Study**

This study aims to compare the efficacy of No-Tox® a proprietary cosmetic formulation vs. a prescription-grade formulation with 0·05% Tretinoin in improving the appearance of facial wrinkles.

**1.2 Type of Data**

We will collect quantitative and qualitative data from 3-D facial scanner measurements of wrinkle depth, and the completion of questionnaires by participants.

**1.3 Format and Scale of Data**

The majority of raw quantitative data will be stored in Microsoft Excel or Microsoft Word format with statistical analysis performed by the Auckland University of Technology Department of Mathematical Sciences. Images of participant facial scans will be stored as jpegs in the software associated with the Pear 3D facial scanner that uses proprietary software. However, images can be exported as jpegs or pdfs and stored elsewhere.

**2. DATA COLLECTION AND GENERATION**

**2.1 Methodologies for data collection / generation**

Data analysis standard operating procedures have been developed for generation of imaging data by the manufacturers, and all analysis will be carried out in accordance with those documents. All data is electronic and will be stored in a central access database, linking together Excel spreadsheets or Word documents.

**2.2 Data quality and standards**

Consistency and quality of the data collection will be tested at 1 and 3 months by the study data coordinator and passed on for independent analysis. This will include scatter plots of the data and testing for normality. Analytical methods and statistical tests to be applied will be determined independently by the coordinator at the Department of Mathematical Sciences, Auckland University of Technology.

**3. DATA MANAGEMENT, DOCUMENTATION AND CURATION**

**3.1 Managing, storing and curating data**

Data and definitive project documentation will be stored on cloud servers and research storage infrastructure throughout the lifetime of the project. Up to 10TB of storage has been made available to this research project. Access control is by authorised computer account username and password. Off-site access is facilitated by secure connection authenticated by username and remote password. By default, two copies of data are kept and is maintained by the Computer Support Team at the Skin Surgery Clinic.

**3.2 Metadata standards and data documentation**

Methods and SOPs will be stored electronically in Microsoft Word documents and Microsoft Excel spreadsheets containing data.

**3.3 Data preservation strategy and standards**

Data collected in paper form will be routinely digitised and the paper form disposed of. All digital documents will be stored for at least 10 years in our secure cloud servers. We plan to make processed image data available via our server for at least 5 years after the end of this study (from 3 months after the completion of the study).

**4. DATA SECURITY AND CONFIDENTIALITY OF POTENTIALLY DISCLOSIVE PERSONAL INFORMATION**

**4.1 Main risks to data security**

Clinical data in this project will be de-identified. All information is sorted in password-encrypted computers or secure encrypted cloud servers.

**5. DATA SHARING AND ACCESS**

**5.1 Suitability for sharing**

The Study database will be shareable as the data will be anonymised and, in a format, suitable for preservation. Any paper documents will not be shared to protect patient confidentiality and destroyed at the conclusion of the study.

**5.2 Discovery by potential users of the research data**

At the end of the project the results with be published.

**5.3 Governance of access**

The lead investigator and project team [including collaborators if applicable] will review applications to access any experimental data and make the decision on whether to supply research data to potential applicants. Data will then be released on a case by case basis.

**5.4 The study team’s exclusive use of the data**

The project group (including collaborators) will have exclusive use of the data until the main research findings are published for a period of 5 years.

**5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions**

At present we do not foresee any delays in data sharing following publication of the main research findings.

**6. MĀORI DATA SOVEREIGNTY (to comply with New Zealand Treaty of Waitangi obligations)**

During the study, data may be collected from participants identifying as Maori. Personal and health information is a tāonga (treasure) and will be treated accordingly.

If any Māori participant is identified during the registration process, formal local Māori consultation for this study will be undertaken. Any recommendations for additional measures to improve Māori rights and interests in relation to data will be acted upon. The marae, Ngā Wai o Horotiu, attached to the Auckland University of Technology has been designated as the authority the study researchers will receive guidance from.

**7. RESPONSIBILITIES**

In addition to the Principal Investigator (Allanah Knight) the data capture and data management will be supported by the Co-applicant and Coordinator [Sharad Paul] who will oversee the project.

**8. AUTHORSHIP**

Author of this Data Management Plan: Sharad Paul

Principal Investigator: Allanah Knight

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**Signed**

**Sharad Paul \_e-signed Spaul\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Allanah Knight \_\_e-signed AMKnight\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**