SKIN SURGERY CLINIC

INSTITUTIONAL ETHICS APPROVAL

17 Feb 2022

Allanah Knight
Lead Investigator
NOVRET Study

Re: Your application for Institutional Ethics Approval for:
ANZCTR Trial Id: ACTRN12621001735842 Request Id: 382893
Full Name of Trial: A randomised, controlled comparative study the wrinkle reduction benefits of No-Tox, a plukenetia/niacinamide/plankton-based topical cosmeceutical formulation vs. 0.5 mg (0.05% w/w) tretinoin, a pharmaceutical prescription-strength topical retinoic acid formulation in healthy adults
Abbreviation/Acronym: NOVRET Study

The board of the Skin Surgery reviewed your application for Instructional Ethics Approval, and based on standard procedures the following checklist was applied:

CHECKLIST

1. **Registration of Trial with WHO Approved Registry:** √
(ANZCTR Trial Id: ACTRN12621001735842 was noted)

2. **NZ Health and Disability Ethics Committee Approval or Exemption Letter:** √
(HDECS Exemption Letter 10 Jan 2022 was tabled)

3. **Two independent scientific and ethical peer-reviews by academics:** √
(In the event HDECS approval is not required, standard practice of the Institution is to engage two independent international experts who are familiar with skin-related trials; Expert reports were tabled and reviewed)

4. **Data Management and Participant Consent Form:** √
(The Institutional Board reviewed these documents; the Plan and Form were previously approved by two independent experts familiar with trials)

INSTITUTIONAL ETHICS COMMITTEE DECISION: APPROVED
REFERENCE: NOVRET 2022/Ethics (Please quote in any future communication)

Yours sincerely,

AMC Murray
Member Secretary

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011
hdecs@health.govt.nz

10 January 2022

Dr Sharad Paul

Tēnā koe Sharad

Your study will not require submission to HDEC, as on the basis of the information you have submitted, it does not appear to be within the scope of HDEC review. This scope is described in section three of the Standard Operating Procedures for Health and Disability Ethics Committees.

This does not appear to be medical research as cosmeceuticals do not come under the purview of health or disability research.

This is to inform you that your study NOVRET Study (No-Tox v Retinoid Study) is out of scope and does not require HDEC approval.

Please note, your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB's research office before you begin.

If you consider that our advice on your project being out of scope is incorrect, please contact us as soon as possible giving reasons for this.

This letter does not constitute ethical approval or endorsement for the activity described in your application but **may be used as evidence that HDEC review is not required for it.**

Further information and assistance

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our General FAQ and Ethics RM FAQ.

Please don't hesitate to contact the HDEC secretariat for further information.

Yours sincerely,

Mx Robyn Minns

Health and Disability Ethics Committees

hdecs@health.govt.nz

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Scientific Peer Review	NOVRET hdec-peer-review-TD	06/12/2021	
PIS/CF	NOVRET PARTICIPANT CONSENT FORM	28/12/2021	1
Evidence of CI Indemnity	MPS 2020-21	28/12/2021	2021
Data Management Plan	NOVRET Study Data Management plan-2	28/12/2021	
CV for Coordinating Investigator	CV-Sharad 2021	28/12/2021	2021
PIS/CF	NOVRET PARTICIPANT CONSENT FORM	28/12/2021	1
Protocol	HDEC No-Tox STUDY PROTOCOL	28/12/2021	1
Protocol	NOVRET Study Data Management plan-2	28/12/2021	1
Protocol	HDEC No-Tox STUDY PROTOCOL	28/12/2021	1

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

SCIENTIFIC PEER REVIEW:

Date 14-02-2022

Research Title: **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: No-tox Vs. Retinoid Study NOVRET Study)

Lead/Co-coordinating Investigator : **Ms Allanah Knight**

Peer Reviewer Name **Dr Viji Narayanan**

Peer Reviewer Position: **Consultant, Dept. of Dermatology,**

Kings College Hospital, London

Independent from study? **Yes**

Peer Reviewer signature _____

Recommendation: Approve / Revise minor / Revise major / Decline

REVIEW GUIDELINE	GUIDELINE PROMPTS	COMMENTS
Relative merit of the research	• Important, worthwhile and justifiable. • Addresses a health issue that is important for health and/or society. • Aims, research questions and hypotheses build on and address gaps in existing knowledge.	Yes Yes Yes
Design and methods	• Quality of study design • Robustness of the methods used. • Includes a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) proposed methods of data analysis.	Non-biased Randomised with blinded assessor outcomes Yes

	• Timelines for the research included	Yes
Feasibility of the research	• Overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. • Likely to improve scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. • Achievable within the specified timeframe • Researcher/research team has the appropriate experience and expertise.	Yes Yes Yes Yes
Reviewer Independence /objectivity	• Peer review is considered free of bias, equitable and fair. • Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements. • If the peer reviewer is connected to the study please explain what measures are taken to mitigate conflict of interest.	Yes Not connected No conflict of Interest N/A
Ethical Approval	• I do not have any concerns regarding the ethics of the study design or plan and recommend ethical approval be granted.	I totally agree this is an innovative research project addressing the deficit of other options of non-invasive treatment for wrinkles.

Dr. Vijayalakshmy (Viji) Narayanan
Consultant Dermatologist,
Department of Dermatology
Kings College Hospital NHS foundation Trust
LONDON. SE5 9RS.

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C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
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SCIENTIFIC PEER REVIEW:

Date 6 / 12 / 2021

Research Title: **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: No-tox Vs. Retinoid Study NOVRET Study)

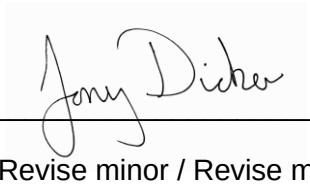
Lead/Co-coordinating Investigator : **Ms Allanah Knight**

Peer Reviewer Name **Assoc Prof Tony Dicker**

Peer Reviewer Position: Senior Lecturer, University of Queensland; Medical Practitioner, Australian Skin Cancer Clinics.

Assoc Prof Tony Dicker is a senior lecturer in the faculty of Medicine at the University of Queensland, where he is Academic Lead and course co-ordinator for the Masters of Medicine (Skin Cancer). He also teaches skin cancer surgery for a number of other professional training organisations. Assoc Prof Dicker obtained his medical degree from Monash University in 1989 and his PhD in Molecular Biology of Skin Cancer from The University of Queensland in 2001

Independent from study? **Yes**

Peer Reviewer signature 

Recommendation: **[**Approve**]** / Revise minor / Revise major / Decline

REVIEW GUIDELINE	GUIDELINE PROMPTS	COMMENTS
Relative merit of the research	• Important, worthwhile and justifiable. • Addresses a health issue that is important for health and/or society. • Aims, research questions and hypotheses build on and address gaps in existing knowledge.	Controlled comparison trials of products are very important in this field. An objective measure of the outcome is of significant benefit
Design and methods	• Quality of study design • Robustness of the methods used.	The design and methods are appropriate. There is an immediate post treatment assessment and a longer term comparison point for efficacy.

	• Includes a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) proposed methods of data analysis. • Timelines for the research included	
Feasibility of the research	• Overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. • Likely to improve scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. • Achievable within the specified timeframe • Researcher/research team has the appropriate experience and expertise.	The measurement system provides objectivity. The size and scope of the trial is feasible
Reviewer Independence /objectivity	• Peer review is considered free of bias, equitable and fair. • Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements. • If the peer reviewer is connected to the study please explain what measures are taken to mitigate conflict of interest.	I'm not linked to the study and do not work with a competitive product. No conflict of interest to declare
Other comments Ethics Approval	• Any reviewer observations that are not covered in the points above. • Any reviewer concerns or recommendations	Exclusion due to pregnancy is appropriate as Tretinoin is listed as a Class D drug I do not have any concerns based on study design and protocols and recommend that ethics approval be granted