# A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the "Cawthon qPCR Assay"



Prepared for:

Ahmad Alkayali
Certified Nutraceuticals
Post Box 1065
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Prepared by:

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Draft Summary Report: 3 July 2018
Draft Summary Report v2: 4 Sept 2018
Fina Summary Report: 4 Sept 2018

**A HOME USE STUDY IN HEALTHY VOLUNTEERS TO ASSESS EFFECTIVENESS OF A DIETARY SUPPLEMENT TO HALT THE SHORTENING OF TELOMERE LENGTH AS DEMONSTRATED BY THE "CAWTHON QPCR ASSAY"**

**Princeton Consumer Research Corp. Summary Report No: CERTEL1F**

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by Princeton Consumer Research Corp. were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Lynne M. Ellis
(Principal Investigator)

Lynne M Ellis MD

Date 9/7/18

Chloe Browne
(Project Manager)

Date 7 Sep 2018

**QUALITY ASSURANCE STATEMENT**

This Summary report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

Anne Campbell, BS
(Quality Assurance Manager)

Anne Campbell

Date 7 Sep 2018

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# 1 SUMMARY


Protocol Title: A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the "Cawthon qPCR Assay"

Study design: Randomized Controlled study design with two treatment groups, subjects acted as their own control

Test Article: 1. Telos 95® Dietary Supplement

Number of subjects: Fifty-nine (59) subjects were screened and enrolled and fifty (50) subjects completed the study.

Type of subjects: Healthy male/female subjects aged 30 to 60 years of age.

Method: This study was a randomized controlled design in approximately fifty (50) healthy adult subjects. Qualified subjects provided a small blood sample via finger stick at their baseline visit. The blood samples were sent to Telomere Diagnostics Inc. for analysis of telomere length which is used to calculate average telomere length (ATL). Subjects were randomized into one of two treatment groups: test article once per day (Group A) or twice per day (Group B). Subject were provided the test article, a diary to ensure compliance and instructions for use of the test product.

Conclusion: A total of fifty (50) subjects completed all aspects of the study. Group A decreased their "TeloYear" age on average by 7.43 years. Group B decreased their "TeloYear" age on average by 8.52 years.

Average telomere length (ATL), also represented as the T/S ratio, showed a baseline measurement of 0.85 but after taking the product for 6 months it increased to 0.95. Group B baseline ATL measured 0.82 at baseline and increased to 0.94 post 6 months of test article usage.

Duration of study: Study Started: 23 March 2017
Study Ended: 25 April 2018

Clinical Location: Princeton Consumer Research Corp.
Baypoint Commerce Center
9600 Koger Blvd., Suite 120
St. Petersburg, FL 33702

Diagnostic Lab: Telomere Diagnostics, Inc.
3603 Haven Ave. A.
Menlo Park, CA 94025

## 2 KEY STUDY PERSONNEL AND RESPONSIBILITIES

| Key Personnel | General Responsibilities |
|---|---|
| **Principal Investigator (PI)**<br>Lynne M. Ellis<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL 33702<br><br>Tel: 727.576.7300 | The Principal Investigator (PI) was responsible for ensuring sufficient resources were available to conduct the study and was responsible for the study design and conduct, subject safety, review of the study protocol and study report. |
| **Study Supervisor (SS)**<br>Tracy Gelo<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL 33702<br><br>Tel: 727.576.7300 | The Study Supervisor (SS) was responsible for the conduct of the study on a daily basis. |
| **Project Manager (PM)**<br>Chloe Browne<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. N, Suite 120<br>St. Petersburg, FL 33702<br><br>Tel: 727.576.7300 | The Project Manager was the primary point of contact and represented the site (Princeton Consumer Research) for this study. |
| **Project Coordinator (PC)**<br>Ahmad Alykayli<br>Certified Nutraceuticals<br>Post Box 1065<br>Pauma Valley, CA 92061<br><br>Tel: 951-600-3899 | The Project Coordinator (PC) was the primary point of contact on behalf of the sponsor of this study and represented the Sponsor of this study (Certified Nutraceuticals). |

## 3 BACKGROUND

Telomeres are functional complexes at the base of eukaryotic chromosomes. They help to maintain and prevent deterioration of the cells. Shorter telomeres have been shown to be the cause of aging and become shorter due to the aging process and an unhealthy lifestyle. The shorter the telomere becomes, the less it can prevent cell death due to the cell no longer being able to divide properly. Telomerase consists of RNA subunits and proteins which aids in elongating telomeres. This lengthening process occurs by adding DNA base-pair sequences to the ends of chromosomes. (Certified Nutraceuticals , 2014-2016).

## 4 OBJECTIVE

The objective of this study was to assess the efficacy of a dietary supplement to prevent the telomere shortening when taken over a six-month period. The study compared the baseline telomere results for subjects to results obtained after six months of test article usage. The analysis measures individual's average telomere length (ATL) and provides a "TeloYears" age based on how the subject's Average Telomere Length (ATL) compares to others of the same age and gender.

## 5 STUDY DESIGN

Single-center, 6-month study to determine pretreatment baseline average telomere length and a post treatment average telomere length after 6 months of supplement use.

## 6 SELECTION OF SUBJECTS

### 6.1 Screening

An adequate number of subjects were screened and enrolled so that a minimum of 50 subjects would complete the study. Subjects had to satisfy the following inclusion and exclusion criteria, and had to give written informed consent.

The suitability of each subject to participate was confirmed prior to their acceptance onto the study by completion and review of a study specific inclusion and exclusion criteria as well as an assessment by the expert grader and subjective assessments.

### 6.2 Inclusion criteria

a) Healthy volunteers, 30 to 60 years of age

b) Completed written informed consent containing HIPAA authorization.

### 6.3 Exclusion criteria

a) Female subject is pregnant, nursing or planning to become pregnant (Verbal response only)

b) Subject is an insulin-dependent diabetic.

c) Subject has a disease which, in the opinion of the Investigator, would compromise the safety of the subject or the validity of the study outcome.

d) Subject has a heart condition or a history of heart issues, which, in the opinion of the Investigator, would compromise the safety of the subject or the validity of the study outcome.

e) Subject has a medical history which, in the opinion of the Investigator, would compromise the safety of the subject or the validity of the study outcome.

f) Subject has a history of any malignancy or tumor.

### 6.4 Prohibitions and Restrictions for the Duration of the Study

a) Subject agrees to attend all test facility appointments and follow all study instructions.

b) Subject agrees not to use any antioxidant supplements or dietary supplements that are intended for telomere enhancements for the duration of the study.

### 6.5 Subject Withdrawal

The participation of a subject in this study may have been discontinued for any of the following reasons:

- An Adverse Event that requires study article to be discontinued
- Withdraws consent to continue participation in the study
- Protocol violation (including lack of compliance)
- Other reasons, such as administrative reasons.

Subjects who prematurely dropped out of the study were not replaced.

## 7 TEST ARTICLES

The test article was supplied by the Sponsor:

1. Telos 95® Dietary Supplement

| Randomization – Amount of Daily use of Test Article | |
|---|---|
| A | Usage of one capsule once a day |
| B | Usage of one capsule twice a day |

The test article was used as supplied by the Sponsor according to the use instructions provided by the Sponsor in the protocol.

The Sponsor provided the Free Trade Certificate from the FDA for the test article.

The Sponsor provided the INCI listings.

It was the responsibility of the Sponsor to determine, for each batch of test article, the identity, strength, purity, composition, and other characteristics which appropriately defined the test article before it was used in the study. The determination of its stability and documentation of methods of synthesis and derivation were also the Sponsor's responsibility.

It was the responsibility of the Sponsor that the test article met all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods, and that any costs including tax/duty are fully met by the Sponsor prior to receipt of the test article at Princeton Consumer Research Corp. No liability with regard to safe receipt or costs involved in carriage of goods to any Princeton Consumer Research Corp. site would be accepted.

On study completion, all remaining used/unused test articles were disposed of by site, unless otherwise requested by the Sponsor after issuance of final report or 28 days after study completion, whichever came first. Sponsors requesting the return of products were liable for any costs incurred.

# 8 STUDY PROCEDURE

### Changes in Study Design

The study commenced on 23 Mar 2017 and was originally written as a yearlong study design. Subjects were consented, screened, participated in a cheek swab procedure and were given instructions to not use any antioxidant products. Subjects were instructed to return to the site 6 months.

Before the subjects returned for their second visit, the testing site discovered that the lab (Titanovo, Inc.), that was originally used to analyze the swabs, was sued due to patent infringement by Telomere Diagnostics, Inc. With this, the study had to be revamped. The sponsor and PI were contacted. Telomere Diagnostics, Inc was contacted to create a new study design. A Protocol Amendment was created to reflect the changes. The Informed Consent Form was amended.

All subjects were called and informed of the study design changes. The subjects were asked if they still wanted to participate in the newly revamped study. Subjects were given a return appointment time to be reconsented and participated in the finger stick procedure now laid out in the updated consent form.

### Visit 1 – Screening

A sufficient number of were screened and enrolled on to the study to ensure that a minimum of 50 subjects completed all phases of the study. Qualified subjects had a small blood sample collected via finger stick using the telomere diagnostic collection kit provided by the diagnostic lab (Telomere Diagnostics Inc.). Subjects were assigned to one of two treatment groups (A or B) according to the randomization. Group A was instructed to take one capsule once a day, preferably with a meal. Group B was instructed to take one capsule twice a day, one capsule in the morning and one capsule in the evening and each preferably with a meal.

Blood sample collection kits were sent to Telomere Diagnostics Inc. for analysis.

The test products were to be taken daily at home for the following 6 months of the study according to the usage instructions provided. Subject were given a diary to fill out every day each time they took the product.

### Visit 2 – Month 6 – End of Study

Subjects returned to the test facility following six months of test product use. Adverse events were reviewed and recorded. Subjects were asked to return any unused test product including empty bottles. Subject compliance with the study instructions and restrictions were assessed and completed diaries were reviewed. A second blood sample (via finger stick) was collected from each subject using the telomere diagnostic collection kit. These samples were sent to the diagnostic lab (Telomere Diagnostics Inc.) for analysis. After the visit was completed, the subject's participation was considered final and they were compensated for their participation.

# 9 ASSESSMENTS

## 9.1 Study Evaluations

Blood samples (via finger stick) were collected using a collection kit provided by the telomere analysis lab. Samples were collected at baseline and sent to Telomere Diagnostics Inc. for analysis. After 6 months of test article use (either once a day or twice a day) subjects returned to PCR for blood sample collection. Blood samples Analysis of the telomere to determine the average telomere length (ATL) was conducted using the Cawthon qPCR assay.

The basic theory is that the ratio of the telomeric signal vs. the single copy gene signal reflects the average length of the telomeres per cell in the sample (Telomere Diagnostics, Inc.). The results of the ATL were used to assign a TeloYear age to each subject based on the comparison of their ATL to others in their same age and gender.

## 10 STUDY ETHICS

### 10.1 Institutional Review Board

This study had a full board review and was approved by Chesapeake Institutional Review Board (IRB) on 2 Feb 2017 (See Appendix 1). Continued approval was obtained on 16 Jan 2018 as outlined in 21 CRF Part 56. The IRB reviewed the protocol, the amendment(s), the informed consent form (ICF), safety information, Investigator's curriculum vitae (CV) and advertisements. Protocol Amendment 1 was created to allow all subjects to participate in multiple studies as not to be lock in to one for such a long period of time and as long as the additional study did not involve an anti-aging supplement. This amendment was effective on 15 Mar 2017 and approved by the IRB on 1 Sep 2017. Protocol Amendment 2 with ICF modifications was created for the changes to the study design with the closing of the first testing lab and became effective 1 Sep 2017. This amendment was approved by the IRB on 15 Mar 2017.

### 10.2 Ethical Conduct

This study was conducted in compliance with applicable Good Clinical Practice (GCP) Regulations, the Standard Operating Procedures of Princeton Consumer Research and the Sponsor's Protocol and Protocol Amendments.

The Sponsor was responsible for the ongoing safety evaluation of the investigational products and will promptly notify participating Investigators and regulatory authorities of findings that could have adversely affected the safety of subjects, impact the conduct of the study, or alter the IRB's approval to continue the study.

### 10.3 Subject Information and Consent

Subject consent was obtained prior to participation in any study conduct as required by the regulatory guidelines (21 CRF Part 50). Subjects were given ample opportunity to read the consent form and have all questions regarding study conduct answered prior to signing the consent form. Each subject was provided with a copy of the ICF to retain for his or her records. The original signed ICF was retained on file at the study center.

### 10.4 Authorization to Disclose Protected Health Information

Subjects were informed of the following information: The purpose of the protected health information (PHI) being collected, the possibility that the PHI may be re-disclosed, the duration of the authorization, the right to revoke the authorization, and the right to refuse signature and limit access to PHI during and following the conduct of the trial. Written authorization to disclose PHI was incorporated into the informed consent process and was obtained prior to the subjects entering the study per Princeton Consumer Research standard operating procedures (SOPs). Each subject was provided with a signed copy of the authorization and the original was retained on file at the study center.

### 10.5 Indemnity provision

The Sponsor was responsible, without regard to legal liability, and would indemnify Princeton Consumer Research Corp., or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration in health or well-being as a result of participation in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of Princeton

Consumer Research Corp. employees or any persons undertaking or involved in the study by arrangement with Princeton Consumer Research Corp.

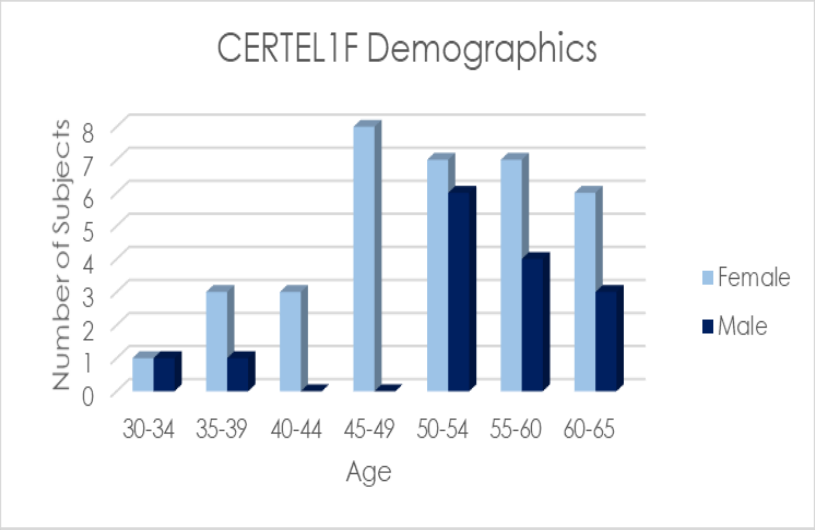
## 11 STUDY DATA

### 11.1 Location and dates of the study

The study was conducted according to the protocol (Appendix 2) at Princeton Consumer Research Corp. from 23 March 2017 to 25 April 2018. The original screening was on 23 Mar 2017. The subjects were reconsented and additional subjects were screened and consented for those subjects that didn't reschedule their second visit on 24 Oct 2017.

### 11.2 Subjects

Fifty-nine (59) subjects were screened and enrolled and fifty (50) subjects completed the study. Please see Appendix 3 for more details on the demographics.




### 11.3 Adverse Events and Severe Adverse Events

There was one Serious Adverse Event on the study that was not related to the Test Product. Subject 45 was hit by a car and was admitted to the hospital. She suffered a broken pelvic bone and a fractured femur.

### 11.4 Discontinued Subjects

Twenty-six (26) subjects discontinued participation on the study. Please see Appendix 4 for details on discontinued subjects.

### 11.5 Deviations

The deviations are listed in Appendix 4.

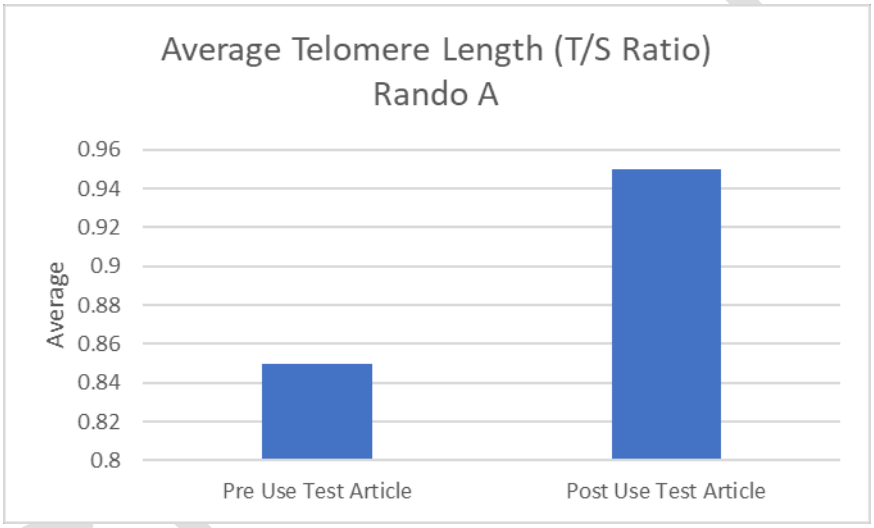
## 12 RESULTS

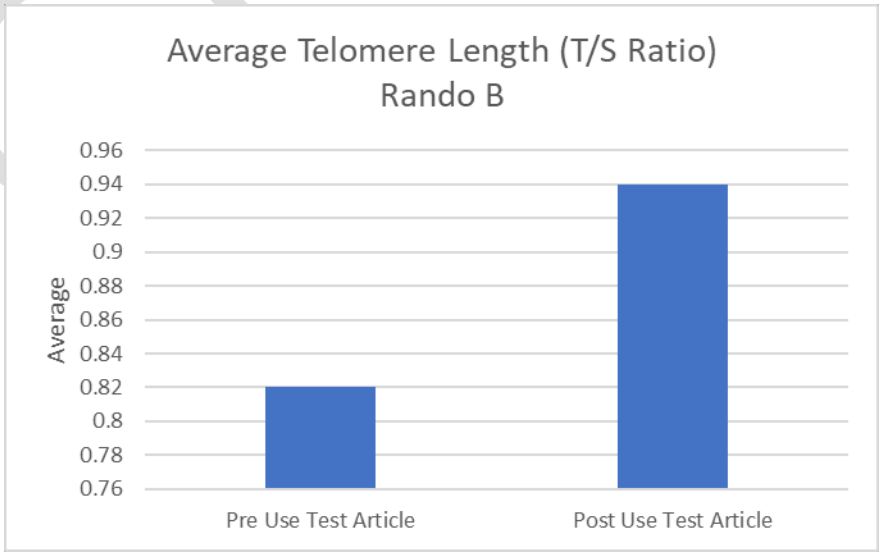
An excel spreadsheet containing the data from the lab was provided to the Sponsor on 19 June 2018. See Appendix 5 full details of the data.

| Average TeloYears Age Decrease | |
|---|---|
| **A** | -7.43 |
| **B** | -8.52 |
| **P-value** | 7.42E-01 |

| Average Telomere Length – Rando A | |
|---|---|
| **Pre Use Test Article** | 0.85 |
| **Post Use Test Article** | 0.95 |
| **P-value** | 4.19E-02 |

| Average Telomere Length – Rando B | |
|---|---|
| **Pre Use Test Article** | 0.82 |
| **Post Use Test Article** | 0.94 |
| **P-value** | 1.75E-03 |



## 13 CONCLUSION

A total of fifty (50) subjects completed all aspects of the study. Group A decreased their "TeloYear" age on average by 7.43 years. Group B decreased their "TeloYear" age on average by 8.52 years.

Average telomere length (ATL), also represented as the T/S ratio, showed a baseline measurement of 0.85 but after taking the product for 6 months it increased to 0.95. Group B baseline ATL measured 0.82 at baseline and increased to 0.94 post 6 months of test article usage.

# CONTINUING REVIEW APPROVAL

CR00081144

| | |
|---|---|
| **DATE:** | 16 Jan 2018 |
| **TO:** | Lynne Ellis, MD<br>Princeton Consumer Research |
| **PROTOCOL:** | Princeton Consumer Research - CERTEL1, A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay (Pro00020464) |
| **CONTINUING REVIEW APPROVAL DATE:** | 16 Jan 2018 |
| **EXPIRATION DATE:** | 16 Jan 2019 |

## IRB APPROVED DOCUMENTATION:

**Protocol Version:**

- Protocol CERTEL1 (Version: Protocol Amendment 2, Date: 25 August 2017)

Thank you for providing the information required for Chesapeake IRB to conduct continuing review of the protocol and your site.

In addition to the information you provided, the IRB reviewed the current protocol referenced above, the Consent Form for the study, and other supporting information.

The IRB approved continuation of the above referenced protocol. The IRB determined changes to the Consent Form were not necessary.

A Continuing Review reminder will be sent prior to your expiration date.

Please review the IRB Handbook located in the "Reference Materials" section of CIRBI™ (www.cirbi.net). A copy of the most recent IRB roster is also available.

We look forward to continuing to work with you on this project.



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chesapeakeirb.com | Office: 410.884.2900 | Fax: 410.884.9190

# APPROVAL WITH MODIFICATIONS

MOD00225688

| | |
|---|---|
| **DATE:** | 5 Sep 2017 |
| **TO:** | Lynne Ellis, MD<br>Princeton Consumer Research |
| **PROTOCOL:** | Princeton Consumer Research - CERTEL1, A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay (Pro00020464) |
| **APPROVAL DATE:** | 1 Sep 2017 |

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**IRB APPROVED:**

| | |
|---|---|
| **Documentation:** | • Protocol CERTEL1 (Version: Protocol Amendment 2, Date: 25 August 2017) |
| **Consent Form:** | • Informed Consent Form (Chesapeake IRB Approved Version 1 Sep 2017) |

The IRB reviewed the above referenced documentation. The IRB granted approval with modifications to correct formatting only.

The Consent Form referenced above are now available on your CIRBI workspace. **The IRB determined new and currently enrolled subjects need to sign the above referenced Consent Form.**

Please review the IRB Handbook by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage ("My Home") and select the "Reference Materials" tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under "Reference Materials".

Thank you for continuing to use Chesapeake IRB to provide oversight for your research project.



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# PROTOCOL APPROVAL WITH MODIFICATIONS

| | |
|---|---|
| **DATE:** | 2 Feb 2017 |
| **TO:** | Lynne M. Ellis, M.D.<br>Princeton Consumer Research |
| **PROTOCOL:** | Princeton Consumer Research - CERTEL1, A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay (Pro00020464) |
| **APPROVAL DATE:** | 2 Feb 2017 |
| **EXPIRATION DATE:** | 2 Feb 2018 |

**IRB APPROVED DOCUMENTATION:**

| | |
|---|---|
| **Protocol Version:** | • Protocol (Final Version, Dated 19th January 2017) |
| **Consent Form:** | • Informed Consent Form (Chesapeake IRB Approved Version 2 Feb 2017) |
| **Recruitment Material:** | • Recruiting Information: Email to Registered Panelists, Online Advertisement (Not Dated) |
| **Other Material:** | • Certificate of Free Sale (Dated May 02, 2016)<br>• INCI Listing (Not Dated)<br>• Subject Diary (Not Dated)<br>• Subject Instructions (Not Dated) |

The IRB approved the above referenced protocol and your site with modifications to the Informed Consent Form on 2 Feb 2017.

If you wish to have the IRB reconsider the imposed modifications, you may follow the procedures outlined below:

1. Submit supporting documentation that addresses the IRB's concerns.
2. Provide a written justification for relief of any IRB imposed condition.

The above referenced recruitment material is available on your CIRBI workspace under the "IRB Issued Documents" tab.



Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation
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If there are any changes to the IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please review the IRB Handbook by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage ("My Home") and select the "Reference Materials" tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under "Reference Materials".

Thank you for selecting Chesapeake IRB to provide oversight for your research project.



Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation

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# MODIFICATION APPROVAL

MOD00200890

**DATE:** 15 Mar 2017

**TO:** Lynne Ellis, Medical Doctor, Board Certified Pediatrician
Princeton Consumer Research

**PROTOCOL:** Princeton Consumer Research - CERTEL1, A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay (Pro00020464)

**APPROVAL DATE:** 15 Mar 2017

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## IRB APPROVED:

**Documentation:**

- Protocol CERTEL1 (Amendment Effective 13th March 2017)
- Telos95 Label/INCI Listing (Not Dated)

The IRB has reviewed and approved the above referenced documentation.

The IRB determined there were no changes required to the current Consent Form. Please use the Consent Form electronically available on your CIRBI workspace under the "IRB Issued Documents" tab.

Please review the IRB Handbook by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage ("My Home") and select the "Reference Materials" tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under "Reference Materials".

Thank you for continuing to use Chesapeake IRB to provide oversight for your research project.





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# RECRUITMENT MATERIAL APPROVAL

MOD00200892

**DATE:** 14 Mar 2017

**TO:** Lynne Ellis, Medical Doctor, Board Certified Pediatrician
Princeton Consumer Research

**PROTOCOL:** Princeton Consumer Research - CERTEL1, A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay (Pro00020464)

**APPROVAL DATE:** 14 Mar 2017

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## IRB APPROVED:

**Documentation:**

- Email to Registered Panelists, Subject: New Study at PCR CERTEL1F Health Supplement Product (Not Dated)
- Potential Online Advertisement (Not Dated)

The IRB reviewed and approved the above referenced material.

The above referenced material is available on your CIRBI workspace under the "IRB Issued Documents" tab.

If there are any changes to IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please review the IRB Handbook by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage ("My Home") and select the "Reference Materials" tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under "Reference Materials".

Thank you for using Chesapeake IRB to provide oversight for your research project.



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# RECRUITMENT MATERIAL APPROVAL

MOD00197798

| | |
|---|---|
| **DATE:** | 17 Feb 2017 |
| **TO:** | Lynne Ellis, MD<br>Princeton Consumer Research |
| **PROTOCOL:** | Princeton Consumer Research - CERTEL1, A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay (Pro00020464) |
| **APPROVAL DATE:** | 17 Feb 2017 |

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**IRB APPROVED:**

**Documentation:**

- Revised Recruiting Information: Email to Registered Panelists, Online Advertisement (Not Dated)

The IRB reviewed and approved the above referenced material.

The above referenced material is available on your CIRBI workspace under the "IRB Issued Documents" tab.

If there are any changes to IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please review the IRB Handbook by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage ("My Home") and select the "Reference Materials" tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under "Reference Materials".

Thank you for using Chesapeake IRB to provide oversight for your research project.



Full Accreditation
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# SUBJECT MATERIAL APPROVAL

MOD00225690

**DATE:** 31 Aug 2017

**TO:** Lynne Ellis, MD
Princeton Consumer Research

**PROTOCOL:** Princeton Consumer Research - CERTEL1, A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay (Pro00020464)

**APPROVAL DATE:** 31 Aug 2017

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**IRB APPROVED:**

**Documentation:**

- Subject Diaries (Not Dated)

The IRB reviewed and approved the above referenced material.

If there are any changes to IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

Please review the IRB Handbook by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage ("My Home") and select the "Reference Materials" tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under "Reference Materials".

Thank you for using Chesapeake IRB to provide oversight for your research project.



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# PROTOCOL

| | |
|---|---|
| Princeton Consumer Research Study Number: | CERTEL1 |
| Title: | A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay |
| Sponsor: | Certified Nutraceuticals |
| Study Center: | Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL 33702 |
| Version: | Final |
| Date: | 19th January 2017 |

**Confidentiality Statement:**

This confidential document is the property of Princeton Consumer Research Corp. and Certified Nutraceuticals. No information contained herein may be disclosed without the prior written approval of Princeton Consumer Research Corp. or Certified Nutraceuticals.

**Approval:**

| | | | |
|---|---|---|---|
| Signature: | Lynne M Ellis MD | Signature: | ..... |
| Name: | Lynne M. Ellis, M.D. | Name: | Ahmad Alkayali |
| Date: | 1/24/17 | Date: | ..... |
| Principal Investigator (Princeton Consumer Research Corp.) | | Project Coordinator (Certified Nutraceuticals) | |

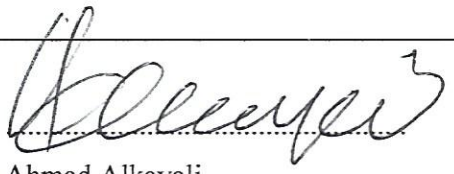
# PROTOCOL

| | |
|---|---|
| Princeton Consumer Research Study Number: | CERTEL1 |
| Title: | A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay |
| Sponsor: | Certified Nutraceuticals |
| Study Center: | Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL 33702 |
| Version: | Final |
| Date: | 19th January 2017 |

**Confidentiality Statement:**



**Approval:**

| | | | |
|---|---|---|---|
| Signature: | ..... | Signature: |  |
| Name: | Lynn Ellis, M.D. | Name: | Ahmad Alkayali |
| Date: | ..... | Date: | 1-23-2017 |
| Principal Investigator | | Project Coordinator | |
| (Princeton Consumer Research Corp.) | | (Certified Nutraceuticals) | |

# 1 PROTOCOL SUMMARY

| | |
|---|---|
| Title: | A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the Results of O'Callaghan Telomere Length Assay |
| Study design: | Single-center, 12-month study conducted in two phases, where the first 6 months will be the control (no treatment) phase and the following 6 months, the subjects will enter the treatment phase. |
| Test product: | 1. Telos 95™ |
| Study method: | Subjects will report to the testing facility at which time Informed Consent will be obtained. Medical History and Concomitant Medication will be captured and Inclusion/Exclusion criteria will be verified. If a subject is qualified and enrolled, a non-invasive saliva-based telomere test will be conducted. Subjects will be instructed to stop usage of supplements used for telomere enhancements for the duration of the study, as well as antioxidant supplements. Multivitamins will be an exception. Subjects will then return to the test site at 6 months and adverse events will be reviewed and recorded and buccal saliva swab samples will be taken for saliva-based telomere testing. Randomization will take place and subjects will be divided in to two treatment groups (Group A and Group B). Group A will take the test product once a day and Group B will take the test product twice a day. Subjects will be given the test product and instructions based on this randomization. At the final visit (12 months), subjects will return to the testing facility, adverse events will be reviewed and recorded and buccal saliva swab samples will be taken for saliva-based testing. |
| Duration of study: | Approximately 1 year |
| Number of subjects: | Approximately 50 |
| Type of subjects: | Healthy volunteers aged 30 to 60 years of age |
| Estimated Start Date: | March 2017 |
| Estimate End Date: | April 2018 |
| Location: | Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL 33702 |
| Lab location<br>For telomere results: | Titanovo<br>310 South Harrington Street<br>Raleigh, NC. 27603 |

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## 2 KEY STUDY PERSONNEL AND RESPONSIBILITIES

| Key personnel | General responsibilities |
|---|---|
| **Principal Investigator (PI)**<br>Lynn Ellis, MD<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL. 33702<br><br>Tel: 727-576-7300 | The Principal Investigator (PI) will be responsible for ensuring sufficient resources are available to conduct the study and for reporting any serious adverse events to the Sponsor. |
| **Study Supervisor (SS)**<br>Tracy Gelo<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL. 33702<br><br>Tel: 724-576-7300 | The Study Supervisor (SS) will be responsible for the conduct of the study on a daily basis. |
| **Project Manager (PM)**<br>Chloe Browne<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL. 33702<br><br>Tel: 727-576-7300 | The Project Manager (PM) will be involved with the study design, compiling the results and writing the clinical report. |
| **Project Coordinator (PC)**<br>Ahmad Alkayali<br>Certified Nutraceuticals<br>Post Box 1065<br>Pauma Valley, CA 92061<br><br>Tel: 951- 600-3899 | The Project Coordinator (PC) will be the primary point of contact on behalf of the Sponsor of this project and will represent the Sponsor (Certified Nutraceuticals) of this study. |

## 3 STUDY FLOW CHART

| Study Day | 1 | Month 6 | Month 12 |
|---|---|---|---|
| **Visit** | **1 (Screening)** | **2 (Baseline)** | **3** |
| Informed Consent Obtained | ✓ | | |
| Demographics | ✓ | | |
| Medical History | ✓ | | |
| Concomitant Medications | ✓ | | |
| Inclusion/Exclusion Criteria | ✓ | | |
| Principal Investigator Review of Entrance Criteria | ✓ | | |
| O'Callaghan Telomere Length Assay (Saliva Test) | ✓ | ✓ | ✓ |
| Adverse Event Review and Concomitant Medications | | ✓ | ✓ |
| Issue of Test Product, Instructions, and Diary | | ✓ | |
| Test Product and Diary Return | | | ✓ |

## 4 OBJECTIVE

Telomeres are functional complexes at the base of eukaryotic chromosomes. They help to maintain and prevent deterioration of the cells. Shorter telomeres have been shown to be the cause of aging and become shorter due to the aging process and an unhealthy lifestyle. The shorter the telomere becomes, the less it can prevent cell death due to the cell no longer being able to divide properly. Telomerase consists of RNA subunits and proteins which aids in elongating telomeres. This lengthening process occurs by adding DNA base-pair sequences to the ends of chromosomes. (Certified Nutraceuticals , 2014-2016).

The objective of this study is to assess the efficacy of a dietary supplement created to support Telomere health by slowing down the shortening of telomeres. The study consists of two phases, starting with a 6-month control phase consisting of refraining from the ingestion of any type of telomere enhancing products and antioxidant supplements, followed by a 6-month treatment phase of home use of the test product. Evidence of the slowing of telomere shortening will be demonstrated by the analysis of buccal saliva swabs using the O'Callaghan Telomere Length Assay.

## 5 STUDY DESIGN

This study will be conducted at a single testing facility and will follow a randomized controlled study design. Subjects will be consented and screened at Visit 1. They will be instructed to discontinue the use of any dietary supplements meant for the enhancement of telomeres for the duration of the study with the exception of multivitamins. Subjects will have buccal saliva swab samples collected which will be sent for analysis utilizing the O'Callaghan Telomere Length Assay. These samples will be sent to Titanovo for measurement. Subjects will be given a return appointment for Visit 2 in 6 months. At Visit 2 the subjects will be queried for any changes to their health or medications and compliance with the study restrictions. Subjects will then have a second saliva collection which will be sent for assay. Once the samples are collected, subjects will be randomized to either treatment Group A or Group B. Approximately 25 subjects will be in Group A and approximately 25 subjects will be in Group B. Group A will be instructed to take the test product once a day, and Group B will be instructed to take the test product twice a day, according to the Sponsor's instructions, for the next 6 months of the study. Subjects will also be given a diary to ensure compliance with the test product. After 6 months of taking the test product, subjects will return to the test site for Visit

3. At this time, subjects will be queried for any changes in their health or medications, their compliance with taking the test product and their adherence to the study restrictions will be assessed and a final saliva sample will be collected. Any remaining test article will be collected, as well as the subject's diary. It will be reviewed by the study staff for compliance.

The study has been designed to substantiate the following subjective claims:

- X% of subjects who demonstrate an increase in telomere length
- X% of subjects who do not experience telomere shortening at the same rate as baseline

Please note that it is the responsibility of the sponsor to determine the testing and study designs required for submission to entities such as the Home Shopping Network, QVC, etc.

## 6 SELECTION OF SUBJECTS

### 6.1 Screening

An adequate number of subjects will be recruited into the study to allow for approximately fifty (50) subjects to be enrolled and complete the study. Subjects must satisfy the following inclusion and exclusion criteria, must be prepared to accept the prohibitions and restrictions and must give written informed consent.

The suitability of potential subjects will be confirmed before their acceptance by review of a study specific pretreatment questionnaire.

### 6.2 Inclusion Criteria

6.2.1 Healthy volunteers, 30 to 60 years of age

6.2.2 Completed written informed consent containing HIPAA authorization.

### 6.3 Exclusion Criteria

6.3.1 Female subject is pregnant, nursing or planning to become pregnant (Verbal response only)

6.3.2 Subject is an insulin-dependent diabetic.

6.3.3 Subject has a disease which, in the opinion of the Investigator, would compromise the safety of the subject or the validity of the study outcome.

6.3.4 Subject has a heart condition or a history of heart issues, which, in the opinion of the Investigator, would compromise the safety of the subject or the validity of the study outcome.

6.3.5 Subject has a medical history which, in the opinion of the Investigator, would compromise the safety of the subject or the validity of the study outcome.

6.3.6 Subject has a history of any malignancy or tumor.

6.3.7 Subject is currently participating on another clinical trial, including other studies being conducted by Princeton Consumer Research Corp.

### 6.4 Prohibitions and Restrictions for the Duration of the Study

6.4.1 Subject agrees to attend all test facility appointments and follow all study instructions.

6.4.2 Subject agrees not to use any antioxidant supplements or dietary supplements that are intended for telomere enhancements for the duration of the study.

# 7 METHOD

## 7.1 Test Product

To the best of the Sponsor's knowledge, the test product has been formulated and tested to comply with applicable regulations. Following consultation with the Sponsor, Princeton Consumer Research Corp. considers the test product to be safe for human use.

The following test product will be supplied by the Sponsor:

1. Telos 95™

Dosing will either be one capsule QD or one capsule BID.

The test product will be used as supplied by the Sponsor according to the use instructions provided by the Sponsor (Appendix 1).

The Sponsor has provided the Free Trade Certificate from the FDA for the test product.

The Sponsor has provided an ingredients list for the test product.

It is the responsibility of the Sponsor to determine, for each test product, the identity, strength, purity, composition, and other characteristics which appropriately define the test product before its use in the study. The determination of its stability and documentation of methods of synthesis and derivation are also the Sponsor's responsibility.

It is the responsibility of the Sponsor that the test product meets all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods, and that any costs including tax/duty are fully met by the Sponsor prior to receipt of the test product at Princeton Consumer Research Corp. No liability with regard to safe receipt or costs involved in carriage of goods to any Princeton Consumer Research Corp. site will be accepted.

After the use of the test products, remaining unused test product will be returned to Sponsor after issuance of final report or 28 days after study completion, whichever comes first.

## 7.2 Study Procedure

### 7.2.1 Visit 1 – Day 1 – Control Phase

Subjects will report to the testing facility for the screening visit and Informed Consent will be obtained. Medical History and Concomitant Medication will be captured and study inclusion and exclusion criteria will be reviewed. Once the subject's eligibility is confirmed, a buccal saliva swab sample will be collected from each subject. The sample will be sent for analysis using the O'Callaghan Telomere Length Assay. Subjects will be instructed to discontinue or refrain from taking any dietary supplements that are intended for telomere enhancements and antioxidant supplements for the duration of the study. Subjects will be provided a return appointment time for Visit 2 (month 6).

### 7.2.2 Visit 2 – Month 6 – Treatment Phase

At the end of the 6-month Control Phase, subjects will return to the test facility. Adverse events and concomitant will be reviewed and recorded and compliance with the study restrictions will be reviewed. Subjects will have buccal saliva swab samples collected for the same telomere testing as performed at the screening visit. Subjects will be assigned to one of two groups depending on the randomization. Group A will be instructed to take the test product once a day, preferably with a meal. Group 2 will be instructed to take the test product twice a day, one capsule in the morning and one capsule in the evening and each preferably with a meal.

The test product will be taken daily at home throughout the next 6 months of the study according to the usage instructions provided. Subject will be given a diary to fill out every day each time they take the product.

### 7.2.3 Visit 3 – Month 12 – End of Study

Subjects will return to the test facility following six months of taking the test product. Adverse events will be reviewed and recorded. Subjects will be asked to return any unused test product including empty bottles. Subject compliance with taking the test product, completion of the diary and following the study restrictions will be assessed. Buccal saliva swab samples will be collected from each subject. The same telomere analysis will be performed on the samples as at the last two visits. After the visit is completed, the subject's participation will be considered final and they will be compensated for their participation.

## 7.3 Study Evaluations

Saliva samples for the O'Callaghan Telomere Length Assay will be collected at every visit. The buccal swab samples collected in the saliva kits will be sent to Titanovo for analysis. Titanovo is a CLIA approved laboratory. Telomere length is measured using qPCR real time instrumentation. This measurement gives the absolute Telomere length. Each visit's measurements will be collected and compared from Screening, Baseline and Post product usage. These results will be posted to the Titanovo client panel on their website. These results from the assay will report the mean telomere length as well as the changes that occur to the length of the telomeres over time (Titanovo, 2015).

The O'Callaghan Telomere Length Assay method uses an oligomer standard containing 14 TTAGGG telomeric repeats and a standard curve using a single copy gene standard (36B4) to estimate both the mean telomere length per reaction and the mean diploid genome copies for each sample. The telomere length per diploid genome and the length per telomere are then calculated according to the O'Callaghan method. Each of the samples will be repeated in triplicate and the mean results will only be accepted if the standard deviation of the CT was <1Ct. (Titanovo, 2015)

# 8 ANALYSIS OF DATA

The analysis will be performed by Titanovo using the buccal swab samples. The data obtained from the 3 longitudinal cohorts will be used to calculate the effectiveness of the supplementation regimen. Null hypothesis testing will be performed using the appropriate methods. The additional survey data such as age and sex will allow for more testing to be performed to include this data as cofounding variables in the more advanced ANOVA models and/or decision trees, random forests, and support vector machines.

There is no formal sample size calculation for this study. Enrolling an adequate number of subjects to complete with about 50 is considered sufficient for the sponsor to evaluate the data collected for evidence of efficacy.

# 9 ADVERSE EVENTS

An adverse event is anything untoward which happens to a subject during a study, whether or not it is related to the administration of the test article.

An adverse reaction to the test product is an adverse event occurring after the administration of the test product which may be causally related to the test product.

Every adverse event will be recorded and then classified as serious or Non-Serious.

## 9.1 Classification

An adverse event is Non-Serious (sub-classified as Mild, Moderate or Severe) unless it falls into one or more of the following categories when it is classified as Serious.

The event:

- results in death;
- is life threatening;
- requires in-patient hospitalization;
- results in persistent or significant disability/incapacitation;
- is a congenital anomaly/birth defect.

Maximum intensity of Non-Serious adverse events should be assigned to one of the following categories:

Mild: For example, an adverse event which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: For example, an adverse event which is sufficiently discomforting and interferes with normal everyday activities.

Severe: For example, an adverse event which prevents normal everyday activities.

## 9.2 Reporting of Adverse Events

In the event of a Serious Adverse Event, the type, onset, severity, duration, and outcome will be recorded on a Serious Adverse Event Form and the Sponsor will be notified within one business day with a written report following within three business days. The significance of the event will be discussed between the Principal Investigator and Sponsor, however the Principal Investigator reserves the right to withhold further administration pending further information and discussion. The subject's primary physician will also be informed as soon as it is reasonably practicable to do so.

Non-Serious adverse events will be reported to the Sponsor in the final clinical report issued at the conclusion of the study.

## 9.3 Withdrawals

The participation of a subject in this study may be discontinued for any of the following reasons:

- the subject wishes to withdraw.
- if, in the opinion of the Principal Investigator, it is in the best interests of the subject.
- suspected adverse effects/adverse device reactions from the test articles.
- inter-current illness.
- violation of the prohibitions and restrictions (see Section 6.4).
- development of an exclusion criterion.

Subjects are free to withdraw at any time and need not give a reason, but every reasonable attempt will be made to ascertain such reasons. The data for those subjects who are withdrawn from the study will be included in the final Clinical Report but may be excluded from final data analysis.

Subjects will not be followed up after their withdrawal from the study, except in the case of a Serious Adverse Event. Withdrawn subjects will not be replaced

# 10 PREMATURE TERMINATION OR SUSPENSION OF THE STUDY

This study may be prematurely suspended or terminated by Princeton Consumer Research Corp., or the Sponsor. In all cases of premature suspension or termination, Princeton Consumer Research Corp. will promptly inform all study subjects and will provide appropriate therapy and subject follow-up.

If the study is prematurely suspended or terminated by Princeton Consumer Research Corp. without the prior agreement of the Sponsor, Princeton Consumer Research Corp. will inform the Sponsor as soon as possible and will provide the Sponsor with a detailed written explanation of the termination or suspension

## 11 STUDY ETHICS

### 11.1 Independent Review Board - IRB

The study protocol, informed consent document, subject instructions/diary and questionnaires if applicable, and any amendments will be submitted to and approved by an IRB prior to enrolling subjects. The selected IRB must be constituted and operated in compliance with 21CFR Part 56.

### 11.2 Amendments to Protocol

Proposed changes or additions to the authorized protocol will be subject to approval by the Principal Investigator, the Sponsor and the IRB before implementation, except and insofar as Princeton Consumer Research Corp. reserves the right to make unilateral departure from the protocol to eliminate an apparent immediate hazard to subject health.

### 11.3 Subject Consent

Subjects will be informed of the nature, purpose and known risk of the study both orally and in writing and will give their written informed consent before participating in the study. Subjects will be advised that they are free to withdraw from the study at any time without being obliged to give a reason. They will be compensated for their time and inconvenience as indicated in the informed consent form.

### 11.4 Indemnity Provision

The Sponsor shall be responsible, without regard to legal liability, and shall indemnify Princeton Consumer Research Corp., or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration in health or well-being as a result of participation in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of Princeton Consumer Research Corp. employees or any persons undertaking or involved in the study by arrangement with Princeton Consumer Research Corp.

### 11.5 ICH Good Clinical Practices

The study will be carried in accordance with applicable sections of the ICH Guidelines on Good Clinical Practice, 1996 and other recognized guidelines.

### 11.6 Declaration of Helsinki

The study will conform to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013).

## 12 QUALITY ASSURANCE

The draft report will be peer-reviewed for accuracy and completeness of presentation. Additionally, the study may be subject to the following Quality Assurance procedures:

- Review of protocol and protocol amendments for completeness, clarity and adequacy.
- Inspection and/or audit of critical phases of study conduct for compliance with protocol and Princeton Consumer Research Corp. procedures.

The Princeton Consumer Research Quality Assurance Manager, will inform Princeton Consumer Research management of any findings that may affect the integrity of the study.

## 13 REPORTING

### 13.1 Interim Reports

Any unexpected findings during the study will be reported to the Project Coordinator as soon as practicable. A draft report will be sent to the Sponsor and to Princeton Consumer Research Corp. Quality Assurance (QA) based on the timelines agreed upon prior to study authorization. With the exception of the dated signature of the consulting dermatologist and other professional personnel, the draft report will contain all information as will be included in the final report. Comments made by the Sponsor and Princeton Consumer Research Corp. QA may be incorporated into the draft report, after which it will be issued as the final report.

### 13.2 Corrections or Additions to the Final Report

Corrections or additions to the authorized version of the final Clinical Report will be made in the form of an amendment. This amendment will clearly identify the part of the final Clinical Report that is being added to or corrected, and will be signed and dated by the Project Manager after review and acceptance by the QA Manager.

## 14 REFERENCES

1. World Medical Association (2013). "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". JAMA 310 (20): 2191–2194. doi:10.1001/jama.2013.281053

2. International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use. Note for Guidance on Good Clinical Practice, Consolidated Guideline. Step 4, Consolidated Guideline, 1/5/96. CPMP/ICH/135/95.

3. Certified Nutraceuticals.(2014-2016). *Telos95*. Retrieved from Certified Nutraceuticals : http://www.certifiednutra.com/products-telos95.php

4. Titanovo.(2015). *What are Telomeres?* Retrieved 2016, from https://Titanovo.com: https://titanovo.com/docs/whitepaper_titanovo.pdf

# PROTOCOL AMENDMENT 2

Princeton Consumer Research Study Number: CERTEL1

| | |
|---|---|
| Revised Title: | A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the "Cawthon qPCR Assay" |
| Sponsor: | Certified Nutraceuticals |
| Study Center: | Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL 33702 |
| Version: | Protocol Amendment 2 |
| Date: | 25 August 2017 |



**Approval:**

| | |
|---|---|
| Signature: Lynne M Ellis MD | Signature: |
| Name: Lynne M. Ellis, M.D. | Name: Ahmad Alkayali |
| Date: 10/11/17 | Date: 8/30-17 |
| Principal Investigator | Project Coordinator |
| (Princeton Consumer Research Corp.) | ( Certified Nutraceuticals) |

# 1 AMENDMENT 2 SUMMARY

| | |
|---|---|
| Revised Title: | A Home Use Study in Healthy Volunteers to Assess Effectiveness of a Dietary Supplement to Halt the Shortening of Telomere Length as Demonstrated by the "Cawthon qPCR assay" |
| Study design: | Single-center, up to 12-month study to determine pretreatment baseline average telomere length and a post treatment average telomere length after 6 months of supplement use |
| Test product: | 1. Telos 95™ |
| Reason for Revision: | Due to the unexpected closure of the laboratory where the saliva test samples was to have been analyzed, a new laboratory, Telomere Diagnostics. Inc., has been contracted to analyze telomere length for the study. The new testing procedure requires a small blood sample via finger stick to analyze telomere length. A Revised Informed Consent for the study reflecting this new procedure will be obtained from study subjects. No new study visits will be added to the study. At visit 2, Medical History and Concomitant Medications will be reviewed and updated and finger stick samples from willing participants will be collected. Randomization will take place at this visit and subjects will be divided into two treatment groups (Group A or Group B). Group A will take the test product once a day and Group B will take the test product twice a day. Subjects will be given the test product and instructions based on this randomization. At the final visit (Visit 3 - 6 months later), subjects will return to the testing facility, adverse events will be reviewed and recorded and final finger stick samples will be collected and sent for analysis. |
| Duration of study: | Up to 1 year (Remaining study duration is approximately 6 months) |
| Number of subjects: | Approximately 50 |
| Type of subjects: | Healthy volunteers aged 30 to 60 years of age |
| Estimated Start Date: | March 2017 (September 2017 for Amendment 1) |
| Estimate End Date: | April 2018 |
| Testing Facility: | Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL 33702 |
| Laboratory: | Telomere Diagnostics, Inc.<br>3603 Haven Ave, Suite A<br>Menlo Park, California 94025 |

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## 2 KEY STUDY PERSONNEL AND RESPONSIBILITIES

| Key personnel | General responsibilities |
|---|---|
| **Principal Investigator (PI)**<br>Lynn Ellis, MD<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL. 33702<br><br>Tel: 727-576-7300 | The Principal Investigator (PI) will be responsible for ensuring sufficient resources are available to conduct the study and for reporting any serious adverse events to the Sponsor. |
| **Study Supervisor (SS)**<br>Tracy Gelo<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL. 33702<br><br>Tel: 724-576-7300 | The Study Supervisor (SS) will be responsible for the conduct of the study on a daily basis. |
| **Project Manager (PM)**<br>Chloe Browne<br>Princeton Consumer Research Corp.<br>Baypoint Commerce Center<br>9600 Koger Blvd. Suite 120<br>St. Petersburg, FL. 33702<br><br>Tel: 727-576-7300 | The Project Manager (PM) will be involved with the study design, compiling the results and writing the clinical report. |
| **Project Coordinator (PC)**<br>Ahmad Alkayali<br>Certified Nutraceuticals<br>Post Box 1065<br>Pauma Valley, CA 92061<br><br>Tel: 951- 600-3899 | The Project Coordinator (PC) will be the primary point of contact on behalf of the Sponsor of this project and will represent the Sponsor (Certified Nutraceuticals) of this study. |

## 3 REVISED STUDY FLOW CHART

| **Study Day** | **1** | **Up to Month 6** | **Up to Month 12** |
|---|---|---|---|
| **Visit** | **1 (Screening)** | **2 (Baseline)** | **3** |
| Informed Consent Obtained | ✓ | | |
| Revised Informed Consent Obtained | | ✓ | |
| Demographics | ✓ | | |
| Medical History | ✓ | Updated ✓ | |
| Concomitant Medications | ✓ | Updated ✓ | |
| Inclusion/Exclusion Criteria | ✓ | Verified ✓ | |
| Principal Investigator Review of Entrance Criteria | ✓ | | |
| Finger stick for blood samples to be sent for Telomere measurement by quantitative PCR | | ✓ | ✓ |
| Adverse Event Review and Concomitant Medications | | | ✓ |
| Issue of Test Product, Instructions, and Diary | | ✓ | |
| Test Product and Diary Return | | | ✓ |

## 4 REVISED STUDY DESIGN

This study will be conducted at a single testing facility and will follow a randomized controlled study design. Subjects have already been consented and screened at Visit 1. At Visit 1 a saliva sample was obtained from each subject and sent to a laboratory facility for analysis. Subjects had been instructed to discontinue the use of any dietary supplements meant for the enhancement of telomeres for the duration of the study with the exception of multivitamins. Due to unforeseen circumstances, the laboratory conducting the saliva analysis (Titanovo Lab.) closed.

The study sponsor was contacted as was the PI and representatives of a new testing laboratory (Telomere Diagnostics Inc.). The new laboratory uses a different type of PCR assay utilizing finger stick blood samples. This analysis can measure the individual's average telomere length (ATL) and give the TeloYears age based on how the subjects ATL compares to others of the same age and gender.

Subjects will be contacted and asked to attend the testing facility for visit 2. At this visit the new testing procedure will be explained and a Revised Informed Consent will be obtained from willing participants. Medical History and Concomitant Medication will be updated and Inclusion/Exclusion criteria will be verified. Finger stick samples from willing participants will be collected. Subjects will be randomized into one of two treatment groups. Group A will take the test product once a day and Group B will take the test product twice a day. Subjects will be given the test product and instructions based on this randomization. Subjects will also be given a diary to use daily to record supplement usage to ensure compliance with the test product. Finger stick samples will be sent to Telomere Diagnostics Inc. for analysis.

Approximately 6 months later, subjects will return to the testing facility for visit 3, adverse events will be reviewed and recorded and a final finger stick sample will be obtained and sent to Telomere Diagnostics, Inc. for analysis. Any remaining test article will be collected, as well as the subject's diary which will be reviewed by the study staff for compliance.

The study has been designed to help support the following claims:

- X% of subjects who demonstrate an average increase in telomere length
- X% of subjects who do not experience telomere shortening at the same rate as the average baseline assessment

Please note that it is the responsibility of the sponsor to determine the testing and study designs required for submission to entities such as the Home Shopping Network, QVC, etc.

## 5 REVISED METHOD

### 5.1 Test Product

The following test product will be supplied by the Sponsor:

1. Telos 95™

Dosing will either be one capsule QD (Group A) or one capsule BID (Group B).

The test product will be used as supplied by the Sponsor according to the use instructions provided by the Sponsor (Appendix 1).

The Sponsor has provided the Free Trade Certificate from the FDA for the test product.

The Sponsor has provided an ingredients list for the test product.

It is the responsibility of the Sponsor to determine, for each test product, the identity, strength, purity, composition, and other characteristics which appropriately define the test product before its use in the study. The determination of its stability and documentation of methods of synthesis and derivation are also the Sponsor's responsibility.

It is the responsibility of the Sponsor that the test product meets all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods, and that any costs including tax/duty are fully met by the Sponsor prior to receipt of the test product at Princeton Consumer Research Corp. No liability with regard to safe receipt or costs involved in carriage of goods to any Princeton Consumer Research Corp. site will be accepted.

After the use of the test products, remaining unused test product will be returned to Sponsor after issuance of final report or 28 days after study completion, whichever comes first.

### 5.2 Revised Study Procedure

#### 5.2.1 Visit 2 – Up to Month 6 – Treatment Phase

Subjects will be contacted to return to the testing facility. Medical History and concomitant medications will be reviewed and updated and compliance with the study restrictions and inclusion/exclusion criteria will be conducted. Subjects will be informed of the change in study procedures (finger stick and revised analysis) and re-consented. Subjects agreeing to continue on the study will have a finger stick performed where a small drop of blood will be collected using the telomere diagnostic collection kit (Telomere Diagnostics Inc.). Subjects will be assigned to one of two treatment groups (A or B) depending on the randomization. Group A will be instructed

to take the test product once a day, preferably with a meal. Group 2 will be instructed to take the test product twice a day, one capsule in the morning and one capsule in the evening and each preferably with a meal. Telomere sample collection kits will be sent to Teleomere Diagnostics Inc. for analysis.

The test product will be taken daily at home throughout the next 6 months of the study according to the usage instructions provided. Subject will be given a diary to fill out every day each time they take the product.

#### 5.2.2 Visit 3 – Month 12 – End of Study

Subjects will return to the test facility following six months of the test product use. Adverse events will be reviewed and recorded. Subjects will be asked to return any unused test product including empty bottles. Subject compliance with the study instructions and restrictions will be assessed and completed diaries will be reviewed. Subjects will have a finger stick to collect a blood sample using the telomere collection kit which will be sent to the lab (Telomere Diagnostics Inc.) for analysis. After the visit is completed, the subject's participation will be considered final and they will be compensated for their participation.

### 5.3 Revised Study Evaluations

Finger stick blood samples will be collected using a collection kit and sent to Telomere Diagnostics Inc. for analysis. Analysis of the telomere to determine the average telomere length (ATL) will be conducted using the Cawthon qPCR assay.

The basic theory is that the ratio of the telomeric signal vs. the single copy gene signal reflects the average length of the telomeres per cell in the sample (Telomere Diagnostics, Inc.). The results of the ATL will be used to assign a TeloYear age to each subject based on the comparison of their ATL to other in their same age and gender.

## 6 ANALYSIS OF DATA

The determination of ATL will be performed by Telomere Diagnostics through analysis of the blood samples collected. The data obtained from the 2 cohorts will be used to calculate the effectiveness of the supplementation regimen using appropriate statistical methods.

There is no formal sample size calculation for this study. Enrolling an adequate number of subjects to complete with about 50 is considered sufficient for the sponsor to evaluate the data collected for evidence of efficacy.

## 7 ADVERSE EVENTS

An adverse event is anything untoward which happens to a subject during a study, whether or not it is related to the administration of the test article.

An adverse reaction to the test product is an adverse event occurring after the administration of the test product which may be causally related to the test product.

Every adverse event will be recorded and then classified as serious or Non-Serious.

## 7.1 Classification

An adverse event is Non-Serious (sub-classified as Mild, Moderate or Severe) unless it falls into one or more of the following categories when it is classified as Serious.

The event:

- results in death;
- is life threatening;
- requires in-patient hospitalization;
- results in persistent or significant disability/incapacitation;
- is a congenital anomaly/birth defect.

Maximum intensity of Non-Serious adverse events should be assigned to one of the following categories:

| | |
|---|---|
| Mild: | For example, an adverse event which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities. |
| Moderate: | For example, an adverse event which is sufficiently discomforting and interferes with normal everyday activities. |
| Severe: | For example, an adverse event which prevents normal everyday activities. |

## 7.2 Reporting of Adverse Events

In the event of a Serious Adverse Event, the type, onset, severity, duration, and outcome will be recorded on a Serious Adverse Event Form and the Sponsor will be notified within one business day with a written report following within three business days. The significance of the event will be discussed between the Principal Investigator and Sponsor, however the Principal Investigator reserves the right to withhold further administration pending further information and discussion. The subject's primary care physician will also be informed as soon as it is reasonably practicable to do so.

Non-Serious adverse events will be reported to the Sponsor in the final clinical report issued at the conclusion of the study.

## 7.3 Withdrawals

The participation of a subject in this study may be discontinued for any of the following reasons:

- the subject wishes to withdraw.
- if, in the opinion of the Principal Investigator, it is in the best interests of the subject.
- suspected adverse effects/adverse device reactions from the test articles.
- inter-current illness.
- violation of the prohibitions and restrictions (see Section 6.4).
- development of an exclusion criterion.

Subjects are free to withdraw at any time and need not give a reason, but every reasonable attempt will be made to ascertain such reasons. The data for those subjects who are withdrawn from the study will be included in the final Clinical Report but may be excluded from final data analysis.

Subjects will not be followed up after their withdrawal from the study, except in the case of a Serious Adverse Event. Withdrawn subjects will not be replaced

## 8 PREMATURE TERMINATION OR SUSPENSION OF THE STUDY

This study may be prematurely suspended or terminated by Princeton Consumer Research Corp., or the Sponsor. In all cases of premature suspension or termination, Princeton Consumer Research Corp. will promptly inform all study subjects and will provide appropriate therapy and subject follow-up.

If the study is prematurely suspended or terminated by Princeton Consumer Research Corp. without the prior agreement of the Sponsor, Princeton Consumer Research Corp. will inform the Sponsor as soon as possible and will provide the Sponsor with a detailed written explanation of the termination or suspension

## 9 STUDY ETHICS

### 9.1 Independent Review Board - IRB

The study protocol, informed consent document, subject instructions/diary and questionnaires if applicable, and any amendments will be submitted to and approved by an IRB prior to enrolling subjects. The selected IRB must be constituted and operated in compliance with 21CFR Part 56.

### 9.2 Amendments to Protocol

Proposed changes or additions to the authorized protocol will be subject to approval by the Principal Investigator, the Sponsor and the IRB before implementation, except and insofar as Princeton Consumer Research Corp. reserves the right to make unilateral departure from the protocol to eliminate an apparent immediate hazard to subject health.

### 9.3 Subject Consent

Subjects will be informed of the nature, purpose and known risk of the study both orally and in writing and will give their written informed consent before participating in the study. Subjects will be advised that they are free to withdraw from the study at any time without being obliged to give a reason. They will be compensated for their time and inconvenience as indicated in the informed consent form.

### 9.4 Indemnity Provision

The Sponsor shall be responsible, without regard to legal liability, and shall indemnify Princeton Consumer Research Corp., or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration in health or well-being as a result of participation in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of Princeton Consumer Research Corp. employees or any persons undertaking or involved in the study by arrangement with Princeton Consumer Research Corp.

### 9.5 ICH Good Clinical Practices

The study will be carried in accordance with applicable sections of the ICH Guidelines on Good Clinical Practice, 1996 and other recognized guidelines.

### 9.6 Declaration of Helsinki

The study will conform to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013).

## 10 QUALITY ASSURANCE

The draft report will be peer-reviewed for accuracy and completeness of presentation. Additionally, the study may be subject to the following Quality Assurance procedures:

- Review of protocol and protocol amendments for completeness, clarity and adequacy.
- Inspection and/or audit of critical phases of study conduct for compliance with protocol and Princeton Consumer Research Corp. procedures.

The Princeton Consumer Research Quality Assurance Manager, will inform Princeton Consumer Research management of any findings that may affect the integrity of the study.

## 11 REPORTING

### 11.1 Interim Reports

Any unexpected findings during the study will be reported to the Project Coordinator as soon as practicable. A draft report will be sent to the Sponsor and to Princeton Consumer Research Corp. Quality Assurance (QA) based on the timelines agreed upon prior to study authorization. With the exception of the dated signature of the consulting dermatologist and other professional personnel, the draft report will contain all information as will be included in the final report. Comments made by the Sponsor and Princeton Consumer Research Corp. QA may be incorporated into the draft report, after which it will be issued as the final report.

### 11.2 Corrections or Additions to the Final Report

Corrections or additions to the authorized version of the final Clinical Report will be made in the form of an amendment. This amendment will clearly identify the part of the final Clinical Report that is being added to or corrected, and will be signed and dated by the Project Manager after review and acceptance by the QA Manager.

## 12 REFERENCES

1. World Medical Association (2013). "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". JAMA 310 (20): 2191–2194. doi:10.1001/jama.2013.281053

2. International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use. Note for Guidance on Good Clinical Practice, Consolidated Guideline. Step 4, Consolidated Guideline, 1/5/96. CPMP/ICH/135/95.

3. Certified Nutraceuticals.(2014-2016). *Telos95*. Retrieved from Certified Nutraceuticals : http://www.certifiednutra.com/products-telos95.php

4. Cawthon, RM. Telomere measurement by quantitative PCR. Nucl. Acids Res. (2002) 30(10):e47.

5. Cawthon, RM. Telomere length measurement by a novel monochrome multiplex quantitative PCR method. Nucl. Acids Res. (2009) 37(3):e21.

| CERTEL1F Completed Subjects Demographics | | | | | |
|---|---|---|---|---|---|
| Screening No. | SUB NO | AGE | GENDER | RACE | Ethnicity |
| 201 | 1 | 60 | Male | Caucasian | Not Hispanic/Latino |
| 203 | 2 | 58 | Male | Caucasian | Not Hispanic/Latino |
| 204 | 4 | 54 | Female | Caucasian | Not Hispanic/Latino |
| 205 | 3 | 57 | Male | Caucasian | Not Hispanic/Latino |
| 206 | 5 | 54 | Female | Caucasian | Not Hispanic/Latino |
| 208 | 7 | 50 | Male | Caucasian | Not Hispanic/Latino |
| 209 | 8 | 49 | Female | Caucasian | Hispanic/Latino |
| 210 | 10 | 50 | Male | Black | Not Hispanic/Latino |
| 215 | 15 | 51 | Male | Black | Not Hispanic/Latino |
| 218 | 18 | 41 | Female | Caucasian | Not Hispanic/Latino |
| 219 | 19 | 50 | Male | Caucasian | Not Hispanic/Latino |
| 223 | 23 | 54 | Male | Black | Not Hispanic/Latino |
| 224 | 24 | 54 | Female | Black | Not Hispanic/Latino |
| 225 | 25 | 56 | Female | Caucasian | Not Hispanic/Latino |
| 226 | 26 | 56 | Male | Caucasian | Not Hispanic/Latino |
| 228 | 28 | 54 | Male | Black | Not Hispanic/Latino |
| 230 | 30 | 55 | Female | Black | Not Hispanic/Latino |
| 231 | 32 | 54 | Female | Black | Not Hispanic/Latino |
| 232 | 31 | 48 | Female | Black | Not Hispanic/Latino |
| 233 | 33 | 44 | Female | Caucasian | Hispanic/Latino |
| 237 | 37 | 51 | Female | Black | Not Hispanic/Latino |
| 241 | 39 | 59 | Female | Black | Not Hispanic/Latino |
| 240 | 40 | 37 | Female | Black | Not Hispanic/Latino |
| 242 | 41 | 36 | Female | Caucasian | Hispanic/Latino |
| 245 | 44 | 45 | Female | Black | Not Hispanic/Latino |
| 246 | 45 | 47 | Female | Black | Hispanic/Latino |
| 247 | 46 | 47 | Female | Caucasian | Not Hispanic/Latino |
| 254 | 53 | 60 | Female | Black | Not Hispanic/Latino |
| 255 | 54 | 63 | Female | Black | Not Hispanic/Latino |
| 257 | 56 | 33 | Male | Caucasian | Not Hispanic/Latino |
| 258 | 57 | 44 | Female | Caucasian | Not Hispanic/Latino |
| 260 | 59 | 66 | Male | Caucasian | Not Hispanic/Latino |
| 262 | 61 | 57 | Female | Caucasian | Not Hispanic/Latino |
| 263 | 62 | 49 | Female | Caucasian | Not Hispanic/Latino |
| 264 | 63 | 62 | Female | Caucasian | Hispanic/Latino |
| 265 | 64 | 52 | Female | Black | Not Hispanic/Latino |
| 266 | 65 | 37 | Female | Black | Not Hispanic/Latino |
| 268 | 66 | 63 | Female | Caucasian | Not Hispanic/Latino |
| 270 | 68 | 59 | Female | AI/AN | Not Hispanic/Latino |
| 271 | 69 | 63 | Female | Caucasian | Not Hispanic/Latino |
| 272 | 70 | 59 | Female | Black | Not Hispanic/Latino |
| 273 | 71 | 46 | Female | Caucasian | Hispanic/Latino |
| 276 | 74 | 32 | Female | Black | Not Hispanic/Latino |
| 278 | 75 | 37 | Male | Black | Not Hispanic/Latino |
| 267 | 76 | 50 | Female | Black | Not Hispanic/Latino |
| 277 | 77 | 49 | Female | Black | Not Hispanic/Latino |
| 279 | 78 | 57 | Male | Multiracial | Not Hispanic/Latino |
| 280 | 79 | 64 | Female | Caucasian | Not Hispanic/Latino |
| 282 | 81 | 64 | Male | Black | Not Hispanic/Latino |
| 283 | 82 | 57 | Female | Caucasian | Hispanic/Latino |

| Discontinued Subjects | |
|---|---|
| **Subject Number(s)** | **Reason for Discontinuation** |
| 09, 29 | PI dropped due to medical history |
| 06 | Subject withdrew consent |
| 11,12,16,17,20,21, 22,27,34,35,36,43,47, 48,51,52, 55,58,73,80, 13, 14 | Lost to follow-up. Unable to attend all visits. |
| 49 | Subject dropped due to actions on another study. Subject no longer allowed to participate in studies at PCR Corp. |

| Minor Protocol Deviation Log | | | |
|---|---|---|---|
| **Study Code:** | **CERTEL1** | **Site:** | **St. Petersburg** |
| **Protocol Title (Abbreviated):** | **Dietary Supplement to Halt Telomere Shortening** | **Principal Investigator:** | Lynne M. Ellis |

| Ref No. | Subject ID | Deviation Description |
|---|---|---|
| **1** | 01 | Subject missed multiple doses of product usage during the 6-month period. |
| **2** | 05 | Subject missed 1 dose of product usage during the 6-month period. |
| **3** | 23 | Subject missed multiple doses of product usage during the 6-month period. |
| **4** | 24 | Subject missed multiple doses of product usage during the 6-month period. |
| **5** | 30 | Subject missed 1 dose of product usage during the 6-month period. |
| **6** | 37 | Subject missed multiple doses of product usage during the 6-month period. |
| **7** | 39 | Subject missed multiple doses of product usage during the 6-month period. |
| **8** | 41 | Subject missed multiple doses of product usage during the 6-month period due to going on vacation and did not bring product. |
| **9** | 54 | Subject missed multiple doses of product usage during the 6-month period. |
| **10** | 56 | Subject missed multiple doses of product usage during the 6-month period. |
| **11** | 57 | Subject missed multiple doses of product usage during the 6-month period. |
| **12** | 64 | Subject missed 1 dose of product usage during the 6-month period. |
| **13** | 65 | Subject missed 1 dose of product usage during the 6-month period. |

| Subject Number | Rando | Name | Age | Gender | T/S ratio | TY2 Percentile Calculator | TeloYears Age | Improvement in TeloYears Age |
|---|---|---|---|---|---|---|---|---|
| 2 | A | REC | 58 | Male | 0.922556 | 0.535268 | 56 | |
| 2 | A | REC | 59 | Male | 1.014653 | 0.78720557 | 45 | -11 |
| 3 | A | TEN | 57 | Male | 0.851114 | 0.30300374 | 66 | |
| 3 | A | TEN | 58 | Male | 0.87192 | 0.37649487 | 63 | -3 |
| 4 | A | CLB | 54 | Female | 0.810141 | 0.11850832 | 67 | |
| 4 | A | CLB | 55 | Female | 0.819022 | 0.14095593 | 68 | 1 |
| 18 | A | CNP | 41 | Female | 0.848986 | 0.11135083 | 61 | |
| 18 | A | CNP | 42 | Female | 0.892178 | 0.20147711 | 57 | -4 |
| 26 | A | EBW | 57 | Male | 0.889824 | 0.42148984 | 60 | |
| 26 | A | EBW | 57 | Male | 1.106442 | 0.91280113 | 39 | -21 |
| 32 | A | MDM | 55 | Female | 1.096322 | 0.84299974 | 38 | |
| 32 | A | MDM | 55 | Female | 1.206176 | 0.95438671 | 38 | 0 |
| 37 | A | ATR | 51 | Female | 0.844594 | 0.16584706 | 66 | |
| 37 | A | ATR | 52 | Female | 0.888684 | 0.28140596 | 62 | -4 |
| 38 | A | SMJ | 55 | Female | 0.771585 | 0.06652173 | 68 | |
| 38 | A | SMJ | 55 | Female | 0.951383 | 0.49761135 | 55 | -13 |
| 40 | A | NMR | 38 | Female | 0.990526 | 0.41928931 | 41 | |
| 40 | A | NMR | 38 | Female | 1.240947 | 0.92017458 | 29 | -12 |
| 44 | A | CRG | 46 | Female | 0.903021 | 0.2624598 | 57 | |
| 44 | A | CRG | 46 | Female | 0.965351 | 0.43682309 | 48 | -9 |
| 45 | A | TVB | 47 | Female | 0.782796 | 0.05179016 | 64 | |
| 45 | A | TVB | 48 | Female | 0.899557 | 0.27222741 | 58 | -6 |
| 46 | A | SAP | 48 | Female | 0.770197 | 0.04316658 | 64 | |
| 46 | A | SAP | 48 | Female | 1.282128 | 0.97289476 | 34 | -30 |
| 53 | A | FLM | 60 | Female | 0.715322 | 0.02870596 | 70 | |
| 53 | A | FLM | 61 | Female | 0.49563 | 0.01 | 71 | 1 |
| 54 | A | ATR | 54 | Female | 0.886676 | 0.29539763 | 63 | |
| 54 | A | ATR | 54 | Female | 0.957346 | 0.50401669 | 53 | -10 |
| 59 | A | DCM | 66 | Male | 0.800152 | 0.24206666 | 73 | |
| 59 | A | DCM | 67 | Male | 1.044624 | 0.89126194 | 46 | -27 |
| 61 | A | GAG | 57 | Female | 0.841843 | 0.20537137 | 69 | |
| 61 | A | GAG | 58 | Female | 0.743691 | 0.04652737 | 69 | 0 |
| 65 | A | CLL | 37 | Female | 0.85509 | 0.09983605 | 58 | |
| 65 | A | CLL | 37 | Female | 1.02811 | 0.51345256 | 36 | -22 |
| 74 | A | LMT | 32 | Female | 0.991764 | 0.35710339 | 38 | |
| 74 | A | LMT | 32 | Female | 0.678489 | 0.99 | 56 | 18 |
| 75 | A | DAH | 37 | Male | 0.866711 | 0.16915824 | 53 | |
| 75 | A | DAH | 37 | Male | 1.021637 | 0.58596914 | 33 | -20 |
| 77 | A | SEF | 49 | Female | 0.778623 | 0.05383283 | 65 | |
| 77 | A | SEF | 49 | Female | 0.844235 | 0.15129735 | 65 | 0 |
| 79 | A | PK | 64 | Female | 0.769536 | 0.10310501 | 72 | |
| 79 | A | PK | 65 | Female | 0.847 | 0.29102541 | 73 | 1 |
| 81 | A | ELF | 64 | Male | 0.677033 | 0.02557318 | 72 | |
| 81 | A | ELF | 64 | Male | 0.793698 | 0.20763483 | 72 | 0 |
| 82 | A | DB | 57 | Female | 0.793199 | 0.10606702 | 69 | |
| 82 | A | DB | 58 | Female | 0.627947 | 0.01 | 69 | 0 |

| Subject Number | Rando | Name | Age | Gender | T/S ratio | TY2 Percentile Calculator | TeloYears Age | Improvement in TeloYears Age |
|---|---|---|---|---|---|---|---|---|
| 1 | B | GFD | 61 | Male | 0.7761 | 0.144451214 | 71 | |
| 1 | B | GFD | 61 | Male | 0.814656 | 0.237549611 | 71 | 0 |
| 5 | B | WKC | 55 | Female | 0.842359 | 0.190691076 | 68 | |
| 5 | B | WKC | 55 | Female | 1.028596 | 0.709317466 | 45 | -23 |
| 7 | B | CV | 50 | Male | 0.725471 | 0.031679006 | 65 | |
| 7 | B | CV | 51 | Male | 0.674308 | 0.01 | 66 | 1 |
| 8 | B | DPP | 49 | Female | 0.874837 | 0.218709966 | 63 | |
| 8 | B | DPP | 50 | Female | 0.858415 | 0.188526498 | 65 | 2 |
| 10 | B | TAN | 51 | Male | 0.668061 | 0.007825086 | 66 | |
| 10 | B | TAN | 51 | Male | 0.98317 | 0.634218949 | 45 | -21 |
| 15 | B | DLM | 52 | Male | 0.670058 | 0.008964666 | 66 | |
| 15 | B | DLM | 52 | Male | 0.771093 | 0.086298465 | 66 | 0 |
| 19 | B | SFW | 51 | Male | 0.831521 | 0.196673533 | 66 | |
| 19 | B | SFW | 51 | Male | 0.909708 | 0.416186818 | 54 | -12 |
| 23 | B | MOL | 55 | Male | 0.999859 | 0.718219849 | 44 | |
| 23 | B | MOL | 55 | Male | 0.885515 | 0.385946384 | 59 | 15 |
| 24 | B | VJM | 55 | Female | 0.664727 | 0.005129268 | 68 | |
| 24 | B | VJM | 55 | Female | 0.686285 | 0.01 | 68 | 0 |
| 25 | B | SAH | 56 | Female | 0.811035 | 0.131900104 | 68 | |
| 25 | B | SAH | 57 | Female | 0.871318 | 0.282045451 | 67 | -1 |
| 28 | B | TEF | 55 | Male | 0.767464 | 0.094779703 | 68 | |
| 28 | B | TEF | 55 | Male | 1.598557 | 0.99 | 38 | -30 |
| 30 | B | CEI | 55 | Female | 0.817833 | 0.138649649 | 68 | |
| 30 | B | CEI | 56 | Female | 0.978607 | 0.588663476 | 51 | -17 |
| 31 | B | CEG | 49 | Female | 0.806167 | 0.086842244 | 65 | |
| 31 | B | CEG | 49 | Female | 1.06705 | 0.739604974 | 37 | -28 |
| 33 | B | IP | 44 | Female | 0.833072 | 0.102252271 | 62 | |
| 33 | B | IP | 45 | Female | 0.918096 | 0.292498936 | 54 | -8 |
| 39 | B | CRS | 60 | Female | 0.821434 | 0.180838688 | 70 | |
| 39 | B | CRS | 60 | Female | 0.808704 | 0.152980386 | 70 | 0 |
| 41 | B | DMC | 36 | Female | 0.862651 | 0.105982588 | 58 | |
| 41 | B | DMC | 37 | Female | 0.948091 | 0.29286603 | 46 | -12 |
| 56 | B | CWN | 34 | Male | 0.660074 | 0.01 | 57 | |
| 56 | B | CWN | 34 | Male | 0.791222 | 0.045121056 | 57 | 0 |
| 57 | B | PSB | 44 | Female | 0.973782 | 0.438783137 | 47 | |
| 57 | B | PSB | 44 | Female | 1.058836 | 0.671505023 | 36 | -11 |
| 62 | B | CL | 49 | Female | 0.800242 | 0.078805054 | 65 | |
| 62 | B | CL | 50 | Female | 1.04296 | 0.69413107 | 41 | -24 |
| 63 | B | FB | 62 | Female | 0.789347 | 0.127219044 | 71 | |
| 63 | B | F-B | 63 | Female | 0.857117 | 0.300585312 | 71 | 0 |
| 64 | B | CEL | 52 | Female | 0.956757 | 0.479475989 | 52 | |
| 64 | B | CEL | 53 | Female | 1.049393 | 0.738011343 | 41 | -11 |
| 66 | B | DGP | 63 | Female | 1.031279 | 0.787730666 | 49 | |
| 66 | B | DGP | 63 | Female | 1.094129 | 0.888982528 | 42 | -7 |
| 68 | B | SMS | 59 | Female | 0.773173 | 0.084840005 | 70 | |
| 68 | B | SMS | 60 | Female | 0.803525 | 0.142395105 | 70 | 0 |
| 70 | B | JGB | 59 | Female | 0.651315 | 0.004684312 | 70 | |
| 70 | B | JGB | 60 | Female | 0.71514 | 0.028587262 | 70 | 0 |
| 71 | B | TB | 47 | Female | 0.873273 | 0.198641657 | 62 | |
| 71 | B | TB | 47 | Female | 1.042645 | 0.662653872 | 40 | -22 |
| 76 | B | TDR | 50 | Female | 0.985406 | 0.540675143 | 47 | |
| 76 | B | TDR | 51 | Female | 0.951042 | 0.451117553 | 53 | 6 |
| 78 | B | MJC | 57 | Male | 0.852641 | 0.30748957 | 66 | |
| 78 | B | MJC | 57 | Male | 1.054417 | 0.844755864 | 39 | -27 |

| Pre Use - A | | | Post Use - A | |
|---|---|---|---|---|
| Subject Number | T/S ratio (ATL) | | Subject Number | T/S ratio (ATL) |
| 2 | 0.92 | | 2 | 1.01 |
| 3 | 0.85 | | 3 | 0.87 |
| 4 | 0.81 | | 4 | 0.82 |
| 18 | 0.85 | | 18 | 0.89 |
| 26 | 0.89 | | 26 | 1.11 |
| 32 | 1.10 | | 32 | 1.21 |
| 37 | 0.84 | | 37 | 0.89 |
| 38 | 0.77 | | 38 | 0.95 |
| 40 | 0.99 | | 40 | 1.24 |
| 44 | 0.90 | | 44 | 0.97 |
| 45 | 0.78 | | 45 | 0.90 |
| 46 | 0.77 | | 46 | 1.28 |
| 53 | 0.72 | | 53 | 0.50 |
| 54 | 0.89 | | 54 | 0.96 |
| 59 | 0.80 | | 59 | 1.04 |
| 61 | 0.84 | | 61 | 0.74 |
| 65 | 0.86 | | 65 | 1.03 |
| 74 | 0.99 | | 74 | 0.68 |
| 75 | 0.87 | | 75 | 1.02 |
| 77 | 0.78 | | 77 | 0.84 |
| 79 | 0.77 | | 79 | 0.85 |
| 81 | 0.68 | | 81 | 0.79 |
| 82 | 0.79 | | 82 | 0.63 |
| Average | 0.85 | | Average | 0.92 |

| Pre Use - B | | | Post Use - B | |
|---|---|---|---|---|
| Subject Number | T/S ratio (ATL) | | Subject Number | T/S ratio (ATL) |
| 1 | 0.78 | | 1 | 0.81 |
| 5 | 0.84 | | 5 | 1.03 |
| 7 | 0.73 | | 7 | 0.67 |
| 8 | 0.87 | | 8 | 0.86 |
| 10 | 0.67 | | 10 | 0.98 |
| 15 | 0.67 | | 15 | 0.77 |
| 19 | 0.83 | | 19 | 0.91 |
| 23 | 1.00 | | 23 | 0.89 |
| 24 | 0.66 | | 24 | 0.69 |
| 25 | 0.81 | | 25 | 0.87 |
| 28 | 0.77 | | 28 | 1.60 |
| 30 | 0.82 | | 30 | 0.98 |
| 31 | 0.81 | | 31 | 1.07 |
| 33 | 0.83 | | 33 | 0.92 |
| 39 | 0.82 | | 39 | 0.81 |
| 41 | 0.86 | | 41 | 0.95 |
| 56 | 0.66 | | 56 | 0.79 |
| 57 | 0.97 | | 57 | 1.06 |
| 62 | 0.80 | | 62 | 1.04 |
| 63 | 0.79 | | 63 | 0.86 |
| 64 | 0.96 | | 64 | 1.05 |
| 66 | 1.03 | | 66 | 1.09 |
| 68 | 0.77 | | 68 | 0.80 |
| 70 | 0.65 | | 70 | 0.72 |
| 71 | 0.87 | | 71 | 1.04 |
| 76 | 0.99 | | 76 | 0.95 |
| 78 | 0.85 | | 78 | 1.05 |
| Average | 0.82 | | Average | 0.94 |

| Subject Number | Gtoup A Decrease in TeloYears Age |
|---|---|
| 2 | -11 |
| 3 | -3 |
| 4 | 1 |
| 18 | -4 |
| 26 | -21 |
| 32 | 0 |
| 37 | -4 |
| 38 | -13 |
| 40 | -12 |
| 44 | -9 |
| 45 | -6 |
| 46 | -30 |
| 53 | 1 |
| 54 | -10 |
| 59 | -27 |
| 61 | 0 |
| 65 | -22 |
| 74 | 18 |
| 75 | -20 |
| 77 | 0 |
| 79 | 1 |
| 81 | 0 |
| 82 | 0 |
| Average | -7.43 |

| Subject Number | Group B Decrease in TeloYears Age |
|---|---|
| 1 | 0 |
| 5 | -23 |
| 7 | 1 |
| 8 | 2 |
| 10 | -21 |
| 15 | 0 |
| 19 | -12 |
| 23 | 15 |
| 24 | 0 |
| 25 | -1 |
| 28 | -30 |
| 30 | -17 |
| 31 | -28 |
| 33 | -8 |
| 39 | 0 |
| 41 | -12 |
| 56 | 0 |
| 57 | -11 |
| 62 | -24 |
| 63 | 0 |
| 64 | -11 |
| 66 | -7 |
| 68 | 0 |
| 70 | 0 |
| 71 | -22 |
| 76 | 6 |
| 78 | -27 |
| Average | -8.52 |
| P value | 7.42E-01 |