

**“DETERMINING THE IMPACT OF MICRO-NUTRIENT DEFICIENCY ON DAMAGE TO
DNA”**

CONSENT FORM

In consideration of Reach100 (as defined below) agreeing to provide me with the results of the analysis of my blood sample I,

INSERT NAME,

of **INSERT ADDRESS**.....

1. consent to Reach100 Pty Ltd (ABN 4012 075 943) of Level 4, 18 North Terrace, Adelaide, South Australia 5000 (“Reach100”) or their nominee taking a(n) [50-70] millilitres sample of my blood (**Sample**) and forwarding it to CSIRO for the purposes of CSIRO analysing the Sample and scoring it using a CBMN Assay test in order for Reach100 to determine the impact of micro-nutrient deficiency on damage to DNA (the **Analysis**);
2. consent to CSIRO analysing and scoring my Sample using a CBMN Assay test;
3. consent to CSIRO providing the results of the scored Sample to Reach100;
4. understand that the Analysis is not diagnostic nor definitive and that the results of the scored sample or the results of the Analysis are not necessarily susceptible to any firm conclusions but will be used, where appropriate, with other tests that Reach100 may recommend regarding appropriate nutrient levels;
5. understand that Reach100 will be interpreting the results of the scored Sample and that CSIRO will have no role in that process;
6. consent to Reach100 providing the results of the Analysis to my referring doctor or my usual General Practitioner, identified below (“My Referring Doctor” or “My usual General Practitioner”);
7. consent to CSIRO retaining and using any data obtained from the Analysis in accordance with the attached information sheet (“Information Sheet”);
8. understand that CSIRO will retain the lymphocytes from my Sample for a period not exceeding 14 days to allow for any re-testing of the Sample in relation to the Analysis;
9. consent to Reach100 providing the information that I give in response to the attached or like questionnaire (“Questionnaire”) in a de-identified form to CSIRO;
10. consent to the results of the Analysis and the abovementioned information in a de-identified form being included in any publication authored by CSIRO or Reach100;
11. understand that the results of the Analysis and abovementioned information will be considered by Reach100 and My Referring Doctor or usual General Practitioner in determining a treatment regime for me;
12. acknowledge that I have read and understood the Information Sheet regarding the Analysis which I have dated and signed;
13. have had the details of the Analysis and the Information Sheet explained to me by The Reach 100 Doctor and have had an opportunity to discuss and ask questions about the Analysis and the Information Sheet with The Reach 100 Doctor, a qualified medical practitioner;

14. understand that the Analysis will involve me physically and mentally in the manner described in the Information Sheet;
15. understand that the results of the Analysis and the abovementioned information are only two of the components that will be considered by Reach100 and My Referring Doctor in determining a treatment regime for me and will not be used as part of a diagnosis of disease;
16. understand that I am not obligated to come in for follow up consultations with Reach100, but that my health outcomes may be improved with such continued follow up consultations;
17. consent to CSIRO retaining and using data associated with my Sample (including the abovementioned information) in an unidentified form for further medical, research and possible future commercial purposes (**Further Research**);
18. understand that for the purposes of the Further Research, data associated with my Sample (including the abovementioned information) will have all identifiers removed by CSIRO 14 days after providing Reach100 with the score for the Analysis so that it will not be possible for the data and information to identify me and it will not be possible for me to withdraw my consent;
19. understand that other than in relation item 18 above I am free to withdraw from the Analysis at any time by providing a written notice to Reach100 withdrawing my consent and request that all data held by Reach100 associated with the Analysis is returned to me;
20. I am over eighteen (18) years of age;
21. I have been provided with a copy of this consent form, the Questionnaire and the Information Sheet for my records.

Name of Patient

Signature of Patient

Date

Name of Referring Doctor

Signature of Referring Doctor

Date

Name of Witness

Signature of Witness

Date

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DNA”**

INFORMATION SHEET

Please read this information carefully. If having read this information you consent to take part in the Analysis, please sign this form and the attached consent form.

What is the aim of the Analysis?

The aim of the analysis is to determine:

- (a) the impact of micro-nutrient deficiency on damage to DNA; and
- (b) whether it is possible to specify the concentration of minerals and vitamins needed to maintain the genetic material (DNA) of our cells in a healthy state for as long as possible.

What precedent is there for the Analysis?

It has been recently shown in scientific publications (references for these can be obtained from your physician) that risk for cancer may be higher in those individuals with:

- (a) blood cells sensitive to the damage caused to genes (or DNA) by radiation; or
- (b) cells with abnormal DNA content.

This characteristic may depend on whether the individual has good genes for repairing damaged DNA or it may be due to a deficiency in nutrients required for repair of damaged DNA. Research has indicated that Folic acid is one of these key essential nutrients. Results from this Analysis may assist your physician to prescribe specific nutrients which may help repair damaged DNA in human cells and may prevent abnormal DNA content.

Do I need to come in for follow-up?

Your results may give your physician an indication of the amount of various nutrients that are needed to prevent damage to DNA. This will enable Reach 100 or your physician to define more clearly if there is an optimal amount of these nutrients for the prevention of damage to DNA, inefficient repair of DNA and abnormal DNA content. Your physician may recommend that you come in for repeat assessment every 3-6 months in the first year, followed by yearly follow-up.

Possible impact of taking part in the Analysis

In some instances, the fact that you have undertaken testing in relation to your DNA may be a matter which has to be disclosed if:

- (a) you apply for a new life or disability insurance policy or wish to increase the level of cover under your current life or disability insurance policies; or
- (b) you renew your sickness and accidents insurance policy; or
- (c) you take out Private Health insurance or change the level of your cover under a Private Health insurance policy.

You may wish to seek independent advice on this issue before signing the consent form in relation to this Analysis.

Who is involved?

The analysis of your blood and the attribution of a score to your blood test result will be conducted by CSIRO's division of Human Nutrition on behalf of Reach 100. Blood samples will be provided to CSIRO by Reach100 or its nominee.

CSIRO will score the blood sample and provide the results to Reach 100, using encrypted, patient tracking software.

Reach 100 will be responsible for interpreting the score attributed to your blood sample, structuring a nutritional program and determining need for follow-up.

CSIRO will have no role in recommending if you should come in for a repeat assessment.

What is involved?

Your physician will make an assessment based on a health and nutrition survey as to whether or not he/she believes participating in this Analysis could be of benefit to you.

Each patient will be asked to provide one 50 ml blood samples each time he/she comes in for assessment.

Blood collection will be by needle. This may cause some discomfort and some bruising. There is also a remote risk of thrombosis and infection. If any symptoms arise as a result of the blood collection, please contact your physician.

The fresh blood samples will be collected after an overnight fast (starting from 11.00pm the previous day). Patients are advised to eat a healthy breakfast after donation.

Tests to be performed on the blood collected for the Analysis.

The following tests will be performed on the blood collected for the Analysis:

- The initial level of DNA damage, as identified by the procedure developed by CSIRO, and concentration of select micronutrients will be measured in your blood.
- The white blood cells from your blood may be cultured in test tubes under various conditions of vitamin or mineral deficiency. The concentration at which your cells experience the least level of damage to DNA will be determined based on a procedure developed by CSIRO.
- DNA extracted from the blood cells may be tested for some inherited or some acquired genetic changes that may alter the capacity of the cells to function normally (e.g. utilise micronutrients and/or repair DNA).

IS MY PRIVACY PROTECTED?

To assist in protecting your privacy:

- all blood and DNA samples are disposed of 14 days after the test on your blood sample has been completed unless otherwise compelled by law. Only the results are stored;
- CSIRO will provide results back to Reach 100, using sophisticated, encrypted, patient tracking software provided by Reach100; and
- CSIRO will not disclose, other than to Reach 100, your test results or associated data in a form which can be identified as relating to you unless compelled to do so by law.

The results of the Analysis may be published in peer-reviewed scientific journals. However donors of the blood will not be identified in the publications.

WHAT HAPPENS TO THE RESULTS?

Through your relationship with Reach 100 and continued assessment, your results may also be tracked over time.

With your consent CSIRO will retain and use the data associated with your blood sample and the information provided in your questionnaire (in a de-identified format) for inclusion into its databases and this data:

- (a) could be used as a comparison in a de-identifiable form with results obtained from broader population studies to determine wider statistical patient benefits;
- (b) may be used for further research relating to the Analysis, other scientific research or commercial applications.

You will not receive or be entitled to any reward or remuneration for CSIRO's use of the data associated with your sample.

If you do not wish for CSIRO to store and retain any data derived from your blood sample please delete items 7, 17 and 18 on the consent form.

CAN I WITHDRAW?

Other than as stated below you will be free to withdraw from the Analysis at any time and request that all data held by Reach100 associated with the Analysis is returned to you at any time.

To withdraw, please contact Reach100 and they will provide you with a “Withdrawal of Consent” form, which will then be communicated to CSIRO (in a de-identified manner).

CSIRO will hold the data associated with your blood sample and the results of your questionnaire for a period of 14 days after providing Reach100 with the score for the Analysis, after which time the data and information contained in the questionnaire will be retained in a non-identifiable form and it will not be possible for you to withdraw your consent.

There is no need for you to provide any explanation to Reach 100 or CSIRO in relation to the reasons for your withdrawal.

I NEED MORE INFORMATION!

Your physician can provide you with further information and advice.

If you are interested we will provide you with copies of the publications describing the results of the Analysis.

Name of Patient

Signature of Patient

Date

Name of Referring Doctor

Signature of Referring Doctor

Date

Name of Witness

Signature of Witness

Date