



ID request #:

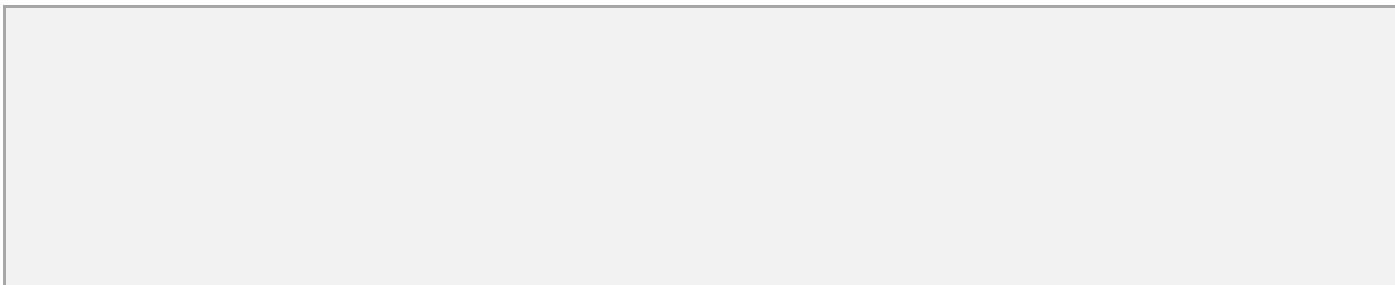
### **Request for Access to Data or Biological Samples from the MAUCO cohort**

The information that is delivered will never include names, IDs, addresses or any other personal information of the participants of MAUCO

<b>1. Main Applicant name</b>	
Research line	
Affiliation	
Telephone and e-mail	
<b>Contact name</b> (Person in charge of communication with MAUCO)	
Telephone and e-mail	
<b>Co-applicant's name</b>	
Telephone and e-mail	
<b>Location for sample processing</b>	

<b>2. Project Details: Refers to what will be studied with data or samples from MAUCO</b>	
Study title	 <hr/> <hr/> <hr/>
Proposed start date of the study using MAUCO data/samples (DD/MM/YYYY)	/ /
Proposed end date of analysis using MAUCO data/samples (DD/MM/YYYY)	/ /
Study aligned with MAUCO objectives	Yes <input type="checkbox"/> No <input type="checkbox"/>

<b>3. Brief description of the study</b>
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4. Funding details:	
The project has been reviewed by peers	Yes <input type="checkbox"/> No <input type="checkbox"/>
Peer-review date (DD/MM/YYYY)	/ /
The project has/had financing	Yes <input type="checkbox"/> No <input type="checkbox"/>
Name of the Institution that finances or has financed	
Funding start date (DD/MM/YYYY)	/ /
Funding end date (DD/MM/YYYY)	/ / Still in place <input type="checkbox"/>
Have funds been considered for the analysis of data and preparation of samples?	Yes <input type="checkbox"/> No <input type="checkbox"/>

5. Ethical Approval:	
The project has ethical approval	Yes <input type="checkbox"/> No <input type="checkbox"/>
Evaluation Committee	
Approval date (DD/MM/YYYY)	/ /
Notes:	
1.	If you are planning on collecting new data/samples in the cohort, you must attach an Informed Consent.
2.	Please attach the approval of the Ethical Committee as an appendix to your application.

6. Access to MAUCO's data: By default, all data are released with indicators of sex and age group	
Will the Project analyze data from all available subjects of the cohort?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If the answer is negative, please define the required subgroup	
Are sex and age group the only variables you need?	Yes <input type="checkbox"/> → go to question 7 No <input type="checkbox"/>

Please indicate which variables you need and justify your request

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**7. New variables created by you or as a result of your analysis**

Describe which variables you expect to generate with your study	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
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To obtain the required data, do you agree to return the new variables created by you or the results of your analyses?	No <input type="checkbox"/> Yes <input type="checkbox"/> Please sign and add the expected return date to MAUCO:  Signature: _____ Date: _____
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Indicate if you require a retention period before other users can access the data requested by you (up to 1 year from the date the data/samples were delivered)	Yes <input type="checkbox"/> No <input type="checkbox"/>
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**8. Biological Samples**

Will the Project require biological samples from the participants of the cohort?	Yes <input type="checkbox"/> No <input type="checkbox"/> (go to question 9)
Where will samples be processed?	

Name and signature of the person responsible for sample processing.			Name: _____  Signature: _____
Type of sample	Mark the requested samples	Minimum amount required	Indicate analysis to be performed
Plasma	<input type="checkbox"/>	_____	_____ _____ _____ _____
Serum	<input type="checkbox"/>	_____	_____ _____ _____ _____
Buffy Coat	<input type="checkbox"/>	_____	_____ _____ _____ _____
DNA	<input type="checkbox"/>	_____	_____ _____ _____ _____
Total Urine	<input type="checkbox"/>	_____	_____ _____ _____ _____
Diluted Urine	<input type="checkbox"/>	_____	_____ _____ _____ _____

Saliva	<input type="checkbox"/>		
Others	<input type="checkbox"/>		
I have reviewed the processing and storage history of the required samples and confirmed that they are adequate for my analyses		Yes <input type="checkbox"/>	No <input type="checkbox"/>
I will provide a copy of the protocols to be used in laboratory analysis and processing.		Yes <input type="checkbox"/>	No <input type="checkbox"/>
I promise to return the results of the analyses obtained in my study.		No <input type="checkbox"/>	Yes <input type="checkbox"/>
		Please sign and add the expected return date to MAUCO: Signature: _____ Date: _____	
		Please add the signature of the technician or professional who will perform the analyses: Signature: _____	
Indicate if you require a retention period before other users can access the data requested by you (up to 1 year from the date where the data/samples were delivered)		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Notes:			
1. Information on the storage history of the samples can be requested from the person in charge of the Biobank: Vanessa Van De Wyngard at vvwandewy@uc.cl			
2. The protocols must be attached as documents annexed to the application			

<b>9. Statistical Analysis</b>	
Name of the person responsible for the statistical analysis of the study	
Affiliation	
Telephone and e-mail	

**Additional Information: Sample Size Calculation**

Please provide a short summary of the SAMPLE SIZE CALCULUS for your study:

**10. Agreement**

**To be completed by the main Applicant:**

a. I confirm that I have read the information provided in this document	Yes <input type="checkbox"/>	No <input type="checkbox"/>
b. The information contained in this application is true	Yes <input type="checkbox"/>	No <input type="checkbox"/>
c. I understand that the information of MAUCO can not be used for commercial purposes	Yes <input type="checkbox"/>	No <input type="checkbox"/>
d. I understand that if my work could be perceived as commercial, it is my responsibility to seek the advice of MAUCO's Advisory Board	Yes <input type="checkbox"/>	No <input type="checkbox"/>
e. I understand that I should not share any data or sample granted or any derived variable to third parties (eg, except for direct employees or one of the main co-applicants).	Yes <input type="checkbox"/>	No <input type="checkbox"/>
f. I understand that a third party who is seeking data or derived variables from this application should approach MAUCO's Advisory Board to obtain his/her own permission	Yes <input type="checkbox"/>	No <input type="checkbox"/>
g. I understand that the agreement for the use of data and samples <u>has a limited duration</u> (according to the dates agreed in question 7 and 8) after which I must deliver/return the data/samples to MAUCO, deleting all the copies that have been made on computers or others devices (if necessary, you can apply for a new access period through a formal letter asking for an extension; this letter should be directed to MAUCO's Advisory Board justifying the request).	Yes <input type="checkbox"/>	No <input type="checkbox"/>
h. I understand that once my study objective is completed, I must return the shared data to the administrator of the MAUCO database/samples and delete all the copies I have on computers or other devices.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
i. I understand that a prior review by MAUCO's Advisory Board or its representatives is necessary for any publication based on MAUCO's data to guarantee its accuracy, quality, validity and ethical aspects.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
j. I understand that recognition of ACCDiS/MAUCO and FONDAP is necessary in all publications and co-authorships as appropriate following the recommendations of the International Committee of Medical Journal Editors (ICMJE) 2014.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
k. The data/samples will be used in accordance with all laws, regulations and ethical requirements.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
l. I understand that I must ensure and protect the confidentiality of the database/samples, keep them in a secure and encrypted location (in the case of data). And that I must keep the data and related confidential information in a secure environment, protected against theft, damage, loss, misuse or unauthorized access.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
m. I understand that if MAUCO data/samples provided for this project are misused – by violating any of the terms and conditions specified in the data/sample transfer agreements that I have signed (as the main applicant), I will be responsible and I will be excluded from the use of MAUCO's resources in the future.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Name: \_\_\_\_\_  
(Applicant)

Signature: \_\_\_\_\_

Name: \_\_\_\_\_  
(Co-Applicant)

Signature: \_\_\_\_\_

Date: / /

Name: \_\_\_\_\_  
(Applicant Institution)

Signature: \_\_\_\_\_

Date: / /

**Please send the complete form to:**

FABIO PAREDES (fparedes@uc.cl)

## 11. Additional information on agreements to share data or samples from MAUCO

Please note that if your application to the MAUCO cohort is successful, the final approval will be subject to the following clauses:

1. The data and samples of MAUCO can not be used for commercial purposes or for any commercial involvement. This would break the basis on which access has been granted
2. Sharing of data or biological samples to third parties is strictly prohibited. Any third party that intends to use the data, samples, variables or derived genotypes must go directly to MAUCO's Advisory Board to obtain the permit in its own right.
3. MAUCO's Advisory Board requires that, whenever possible, individual data created *de novo* be made available to other users, in accordance with the best contemporary practice and taking to account the ethical-legal restrictions and the recognition of the potential risks of the disclosure of the genotypes. If you believe there is any reason why you can not comply with this provision, please contact the MAUCO's Advisory Board Secretariat
4. Once you have been given access to the data, if you require new variables you should contact MAUCO's Advisory Board.
5. Any attempt to identify or jeopardise persons or otherwise violate the confidentiality of the information about the owners of the data and their right to privacy is prohibited.

### 6. **Incidental findings of clinical importance and potential benefits:**

By signing the original consent forms for their inclusion in the MAUCO Study (2014-2016), consenting participants agreed that they would only receive feedback about their baseline clinical examination that does not include any individual genetic results. In the future, it would possible to modify the criterion if the following conditions are met with respect to genetic analysis:

**(i) scientific validity:** genotyping is of adequate quality

**(ii) clinical importance:** the disease or condition caused by the genetic variant is potentially serious

**(iii) the potential benefit:** strategies are available to prevent or cure the condition/disease of interest

**(iv) early knowledge of genetic risk could improve the effectiveness of prevention or cure.**

**For this reason, MAUCO's Advisory Board requires that if in the course of any DNA analysis of any MAUCO participant, a genetic variant is found to potentially fulfill all four of the above criteria, the information must be transmitted to MAUCO's Advisory Board.**

If in the future is necessary to deliver a genetic information to a participant, all these contacts must necessarily be carried out by the MAUCO field team. These requirements will not change even if required by the ethics committee to which the applicant has submitted his study.



**12. Resolution of the application:**

a. The following required data are available and validated:

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Estimated delivery date: ...../...../.....

b. The following information does not exist in the database since it was not collected:

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c. The following requested data was collected, but is not yet available (still in data entry or validation process):

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Estimated delivery date: ...../...../.....

d. The following information is in conflict with a previous requirement of another investigator:

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Catterina Ferreccio  
Director of MAUCO  
Signature Date: ...../...../.....

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Fabio Paredes  
MAUCO Database Manager  
Signature Date: ...../...../.....

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Vanessa Van de Wyngard  
MAUCO Biobank Manager  
Signature Date: ...../...../.....